UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. and MEDTRONIC VASCULAR, INC.,
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.,
Patent Owner

IPR2020-00130
Patent RE45,380

PETITIONERS MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.'S NOTICE OF APPEAL UNDER 37 C.F.R. § 90.2(a)

Pursuant to 35 U.S.C. §§ 141-144, 319, and 37 C.F.R.§ 90.2(a), notice is hereby given that Petitioners Medtronic, Inc. and Medtronic Vascular, Inc. ("Medtronic") appeal to the United States Court of Appeals for the Federal Circuit from the Final Written Decision ("Final Written Decision") (Paper No. 103, dated June 7, 2021 (filed under seal); Paper No. 105, dated June 6, 2021 (redacted)), and the Order denying Director review of the Final Written Decision ("Order Denying Director Review") (Paper No. 107, dated August 27, 2021), both entered by the United States Patent and Trademark Office, Patent Trial and Appeal Board ("Board") in IPR2020-00130, and from all underlying orders, decisions, rulings, and opinions. Copies of the Final Written Decision and the Order Denying Director Review are attached hereto as Exhibits A1 (filed under seal), A2 (redacted), and B.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Medtronic further indicates that the issues on appeal may include, but are not limited to, whether the Board erred in determining that claims 3, 4, 8, 9, 14, 18, and 19 of U.S. Patent Number RE45,380 were not shown to be unpatentable under 35 U.S.C. § 103, any findings supporting or related to the Board's determination, and all other issues decided adversely to Medtronic in any order, decision, ruling, and/or opinion, including but not limited to the Board's failure to properly consider evidence of record, the Board's legal errors in undertaking the obviousness analysis, the Board's findings

that conflict with the evidence of record and are not supported by substantial evidence, and the Board's granting of Teleflex's contingent motion to amend to substitute claims 43 and 44.

Simultaneous with this submission, a copy of this Notice of Appeal is being filed through the Patent Trial and Appeal Board End to End ("PTAB E2E") System. In addition, a copy of the Notice of Appeal, along with the required docketing fee, is being filed with the Clerk of Court for the United States Court of Appeals for the Federal Circuit.

Dated: September 27, 2021

Respectfully submitted,

/s/ Cyrus A. Morton

Cyrus A. Morton
ROBINS KAPLAN LLP
800 LaSalle Avenue, Suite 2800
Minneapolis, MN 55402
(612) 349-8500
Attorney for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that on this September 27, 2021, a copy of Petitioners Medtronic, Inc. and Medtronic Vascular, Inc.'s Notice of Appeal Under 37 C.F.R. § 90.2(a) was served in its entirety by electronic mail on Patent Owner's counsel at the following addresses included in Patent Owner's Mandatory Notices:

J. Derek Vandenburgh, Reg. No. 32,179
dvandenburgh@carlsoncaspers.com

Dennis C. Bremer, Reg. No. 40,528
dbremer@carlsoncaspers.com

Joseph W. Winkels
jwinkels@carlsoncaspers.com

Peter M. Kohlhepp
pkohlhepp@carlsoncaspers.com

Tara C. Norgard
tnorgard@carlsoncaspers.com

Alexander S. Rinn
pkohlhepp@carlsoncaspers.com

Megan E. Christner, Reg. No. 78,979
mchristner@carlsoncaspers.com

Kenneth E. Levitt, Reg. No. 39,747
levitt.kenneth@dorsey.com

Dated: September 27, 2021

Respectfully submitted,
/s/ Cyrus A. Morton
Cyrus A. Morton
Reg. No. 44,954
Attorney for Petitioners

EXHIBIT A1
(Redacted in Full)

EXHIBIT A2

Trials@uspto.gov
571-272-7822

Paper
Date:

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. and MEDTRONIC VASCULAR, INC.,
Petitioner,

v.

TELEFLEX INNOVATIONS S.À.R.L.
Patent Owner.

IPR2020-00130
Patent RE45,380

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

TORNQUIST, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Some Claims Unpatentable
Granting Patent Owner's Contingent Motion to Amend
35 U.S.C. § 318(a)

PUBLIC VERSION

I. INTRODUCTION

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–4, 6–9, and 12–21 of U.S. Reissue Patent RE45,380 (Ex. 1401, "the '380 patent"). Teleflex Innovations S.À.R.L. ("Patent Owner"[1]) filed a Preliminary Response to the Petition (Paper 9). Upon review of the Petition and the Preliminary Response, we instituted an *inter partes* review of all claims and grounds set forth in the Petition (Paper 20, "Institution Decision" or "Inst. Dec.").

Patent Owner subsequently filed a Patent Owner Response (Paper 39, "PO Resp.") (redacted version available at Paper 40), Petitioner filed a Reply (Paper 69, "Pet. Reply") (redacted version available at Paper 70), and Patent Owner filed a Sur-Reply (Paper 84, "Sur-Reply") (redacted version available at Paper 85).

Patent Owner also filed a Contingent Motion to Amend (Paper 35, "Motion") requesting that if either of claims 1 or 12 of the '380 patent are determined to be unpatentable, that the Board substitute those claims with proposed substitute claims 43 and 44. Motion 1. Petitioner filed an opposition to the Motion (Paper 72, "Pet. MTA Opp."), Patent Owner filed a reply (Paper 87, "PO MTA Reply"), and Petitioner filed a sur-reply (Paper 93, "Pet. MTA Sur-Reply").

[1] Patent Owner informs us that Teleflex Innovations S.A.R.L has "merged into Teleflex Medical Devices S.A.R.L," who subsequently transferred ownership of the '380 patent to Teleflex Life Sciences Limited. Paper 7, 2.

An oral hearing was held on March 8, 2021, and a transcript of the hearing is included in the record. Paper 102 ("Tr.") (redacted version available at Paper 101).

A. Related Matters

The parties indicate that the '380 patent is the subject of litigation in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn.) and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn). Pet. 4–5; Paper 4, 2. The '380 patent is also at issue in IPR2020-00128, IPR2020-00129, and IPR2020-00131 (institution denied). Paper 4, 2–3; Pet. 5.

The following proceedings before the Board also involve the same parties and related patents: IPR2020-00126 (U.S. Patent No. 8,048,032 B2), IPR2020-00127 (U.S. Patent No. 8,048,032 B2), IPR2020-00132 (U.S. Patent No. RE45,760 E1), IPR2020-00134 (U.S. Patent No. RE45,760 E1), IPR2020-00135 (U.S. Patent No. RE45,776 E1), IPR2020-00136 (U.S. Patent No. RE45,776 E1), IPR2020-00137 (U.S. Patent No. RE47,379 E1), IPR2020-00138 (U.S. Patent No. RE47,379 E1).

B. Real Parties-in-Interest

Petitioner identifies Medtronic, Inc. and Medtronic Vascular, Inc. as the real parties-in-interest and notes that Medtronic plc "is the ultimate parent of both" entities. Pet. 4.

Patent Owner identifies Vascular Solutions LLC, Arrow International, Inc. and Teleflex LLC as the real parties-in-interest, and notes that Teleflex Incorporated is the ultimate parent of each of these entities. Paper 7, 2.

C. The '380 Patent

The '380 Patent is a reissue of U.S. Patent 8,292,850, and claims priority as a division of application No. 11/416,629, filed on May 3, 2006, now U.S. Patent 8,048,032. Ex. 1401, codes (62), (64). The '380 patent relates to catheters used in interventional cardiology procedures and, in particular, to "methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." *Id.* at 1:31–35.

"In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions." *Id.* at 1:44–46. This narrowing is referred to as stenosis. *Id.* at 1:48–49. To treat this stenosis, "it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery." *Id.* at 1:49–52. In this method, a guide catheter is inserted through the aorta and into the ostium of the coronary artery where it is typically seated into the opening or ostium of the artery to be treated. *Id.* at 1:53–57. A guidewire or other instrument is then passed through the lumen of the guide catheter and inserted into the artery beyond the stenosis. *Id.* at 1:39–41, 1:57–59. Crossing the tough lesions, however, may create enough backwards force to dislodge the guide catheter from the ostium of the artery being treated, making it difficult or impossible to treat certain forms of coronary artery disease. *Id.* at 1:59–63.

The system of the '380 patent utilizes a coaxial guide catheter that includes a tapered inner catheter that runs over a standard coronary

guidewire to allow atraumatic placement within the coronary artery. *Id.* at 3:12–15. Figures 1 and 2 of the '380 patent are reproduced below:

Fig. 1

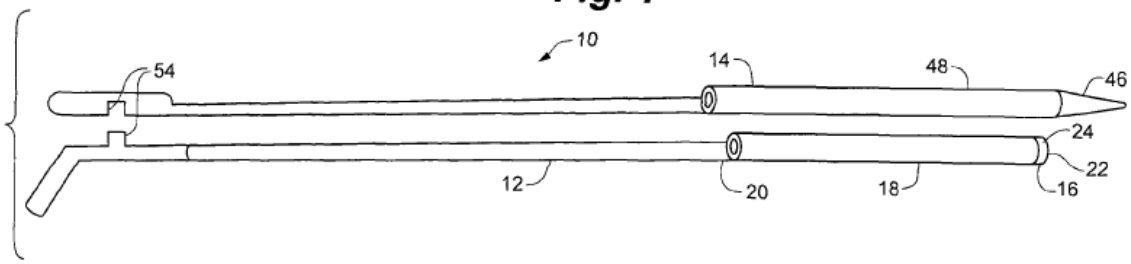


Fig. 2

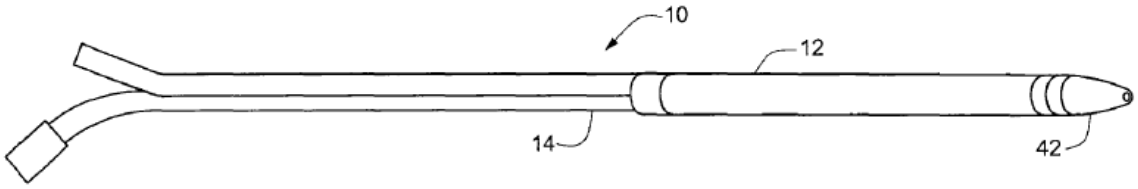


Figure 1 is a schematic depiction of a coaxial guide catheter and a tapered inner catheter and Figure 2 is a schematic depiction of these two elements assembled. *Id.* at 5:40–45. As shown in Figure 1, coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:34–35. Tapered inner catheter 14 includes tapered portion 46 at a distal end thereof and straight portion 48. *Id.* at 7:16–17. Clip 54 releasably joins tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:21–23.

Figure 8 of the ’380 patent is reproduced below:

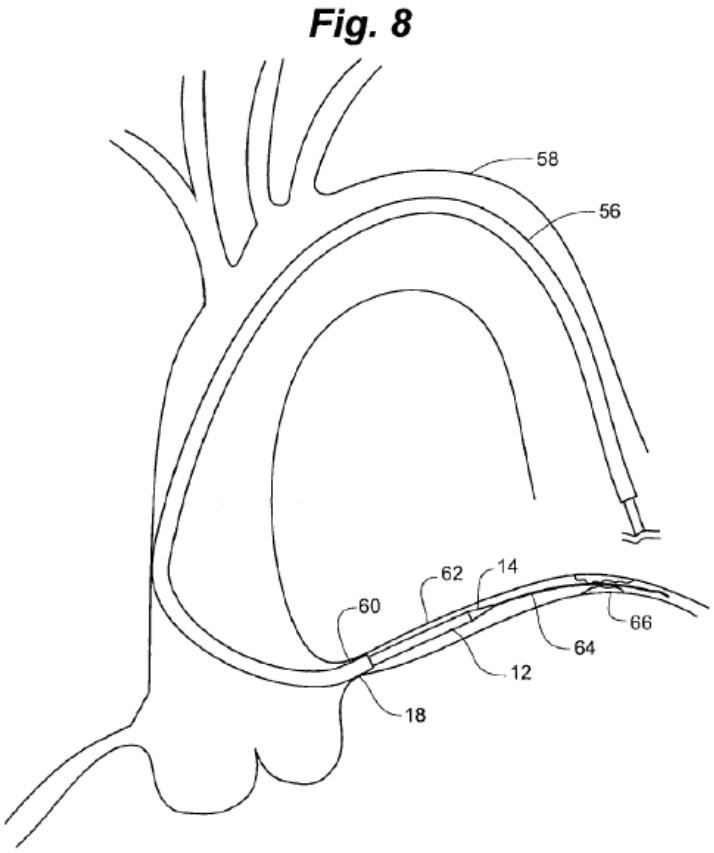


Figure 8 is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter, and a tapered inner catheter located in the aortic arch and coronary artery. *Id.* at 5:61–64. In Figure 8, “coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62 after the guide catheter 56 has been placed in the ostium 60 of coronary artery 62.” *Id.* at 8:6–8. “Coaxial guide catheter 12, with tapered inner catheter 14, provides an inner support member for proper translation over guidewire 64.” *Id.* at 8:11–13. “Once coaxial guide catheter 12 is in place, tapered inner catheter 14 is removed from the inside of coaxial guide catheter 12.” *Id.* at 8:15–17. At this point, coaxial guide catheter 12 is ready to accept a treatment catheter such as a stent or balloon

catheter. *Id.* at 8:18–19. The '380 patent explains that coaxial guide catheter 12 provides additional backup support to resist dislodging of guide catheter 56 from ostium 60 when force is applied to guidewire 64 to pass through stenotic lesion 66. *Id.* at 8:15–30.

D. Illustrative Claims

Independent claim 1 and dependent claim 3 are illustrative of the challenged claims and are reproduced below.

> 1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:
>
> a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and
>
> a device adapted for use with the guide catheter, including:
>
> a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and
>
> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-

sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;

wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.

Ex. 1401, 10:47–11:24 (limitations added by reissue in italics).

3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

Id. at 11:33–40.

E. Prior Art and Asserted Grounds of Unpatentability

Petitioner contends claims 1–4, 6–9, and 12–21 of the '380 patent would have been unpatentable on the following grounds (Pet. 7):

Claims Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1–4, 6, 7, 9, 12–17, 19, 20	103	Kontos[3], Adams[4]
8, 18	103	Kontos, Adams, Takahashi[5]
21	103	Kontos, Adams, Berg[6]

In support of its arguments, Petitioner relies on the expert declarations of Dr. Stephen Jon David Brecker (Ex. 1405, 1806, 1902), Dr. Richard A. Hillstead (Ex. 1442, 1905), Mr. Michael Jones (Ex. 1807), Dr. Paul Zalesky (Ex. 1830, 1919). Patent Owner relies on the declarations of Mr. Peter T. Keith (Ex. 2124, 2138, 2243), Dr. John J. Graham (Ex. 2145), Dr. Lorenzo Azzalini (Ex. 2151), Mr. Steve Jagodzinkski (Ex. 2152 (redacted), 2153 (confidential)), Ms. Amy Welch (Ex. 2043 (confidential), 2044 (redacted)), and Dr. Craig Thompson (Ex. 2215).

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the '380 patent issued was filed before this date, the pre-AIA version of § 103 applies.

[3] Kontos, US 5,439,445, issued August 8, 1995 (Ex. 1409) ("Kontos").

[4] Adams, US 2004/0010280 A1, published January 15, 2004 (Ex. 1435) ("Adams").

[5] Takahashi, et al., *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, Catheterization and Cardiovascular Interventions 63:452–456 (2004) (Ex. 1410) ("Takahashi").

[6] Berg, US 5,911,715, issued June 15, 1999 (Ex. 1451) ("Berg").

II. ANALYSIS

A. Legal Standards

To prevail in its challenge to claims 1–4, 6–9, and 12–21 of the '380 patent, Petitioner has the burden to establish by a preponderance of the evidence that the challenged claims are unpatentable. 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2019). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) if in the record, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art ("POSITA"). Petitioner provides two alternative definitions for a person having ordinary skill in the art. First, Petitioner asserts that if a person of ordinary skill in the art "was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 12. Alternatively, Petitioner asserts that if

a person of ordinary skill in the art was "an engineer s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices." *Id.* Petitioner contends that in its proposed definitions, "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.* at 12–13.

Patent Owner "does not dispute Medtronic's proposed definition of a POSITA." PO Resp. 9.

Upon review of the parties' arguments and supporting evidence, we adopt Petitioner's definitions of a person of ordinary skill in the art, which allow the ordinarily skilled artisan to be either a medical doctor or an engineer, as they are undisputed and consistent with the level of skill reflected in the prior art and the written description of the '380 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

In this proceeding, the claims of the '380 patent are construed "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100(b). Under that standard, the words of a claim are generally given their "ordinary and customary meaning," which is the meaning the term would have had to a person of ordinary skill at the time of the invention, in the context of the entire patent including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

For purposes of this decision, only the term "interventional cardiology devices" requires construction. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

"interventional cardiology devices"

Claims 1 and 12 require a flexible tip portion defining a tubular structure with "a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable." Ex. 1401, 10:58–67, 12:17–28. The '380 patent expressly defines the term "interventional cardiology devices" as follows:

> For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters.

Id. at 1:41–44.

In view of the express definition provided in the '380 patent and the discussion in the '380 patent of using a guide catheter that is sized to receive a guidewire and a stent or balloon, in the Institution Decision, we construed claims 1 and 12 to require that the coaxial lumen have a cross-sectional inner diameter through which at least two types of interventional cardiology devices (including, but not limited to guidewires, balloon catheters, stents, and stent catheters) are insertable. Inst. Dec. 10 (citing Ex. 1401, 7:60–64).

Petitioner contends that claims 1 and 12 require that only one interventional cardiology device be insertable through the cross-sectional inner diameter of the coaxial lumen. Pet. 31, 60–61. Patent Owner contends

claims 1 and 12 require that all four of the enumerated classes of devices identified in the definition of "interventional cardiology devices," i.e., "guidewires, balloon catheters, stents, **and** stent catheters," are insertable through the cross-sectional inner diameter of the coaxial lumen. PO Resp. 9–10. Patent Owner reasons that the use of the conjunctive "and," rather than the disjunctive "or," in the definition indicates that all of the identified "interventional cardiology devices" must be insertable through the coaxial lumen of the flexible tip portion. *Id.* at 10. According to Patent Owner, this conclusion is consistent with the written description of the '380 patent because the "Summary of the Invention" section notes that the "invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel," and guidewires, balloon catheters, stents, and stent catheters are four of the most common coronary devices. *Id.* at 11 (citing Ex. 1401, 3:24–27, 5:33–36; Ex. 2145 ¶ 85; Ex. 2138 ¶ 104).

In its Reply, Petitioner reiterates its position that only one interventional cardiology device need be insertable through the coaxial lumen of the tip portion, but because resolution of the question of whether one or two devices must be insertable into the lumen does not impact the outcome in this case, Petitioner asserts that "the Board can adopt its preliminary construction of 'interventional cardiology devices'" in this proceeding. Pet. Reply 1–2. Responding to Patent Owner's arguments, Petitioner contends that because the term "standard coronary devices" is broader than the specific set of "interventional cardiology devices" identified in the written description, the intrinsic record does not support limiting the scope of claims 1 and 12 to require that the coaxial lumen of the tip portion have a cross-sectional inner diameter through which all four of the

"interventional cardiology devices" expressly identified in the '380 patent are insertable. *Id.* at 2 (citing Ex. 1800, 63:20–64:1).

As both parties agree, the '380 patent expressly defines the term "interventional cardiology devices" to include, but not be limited to, "guidewires, balloon catheters, stents and stent catheters." We understand this definition to mean that "guidewires," "balloon catheters," "stents," and "stent catheters," are each "interventional cardiology devices." *See* Ex. 1401, 5:2–5 ("This discussion will refer to a guide wire but it is to be understood that similar principles apply to other interventional cardiology devices including balloon catheters and stent catheters."). The use of the conjunctive "and" in the definition is consistent with this understanding, as all the listed devices are "interventional cardiology devices." *See id.*

We further understand that an individual guidewire or stent represents an "interventional cardiology device." Pet. 31 (identifying Kontos's PTCA catheter as an "interventional cardiology device"); PO Resp. 22 ("Thus, the PTCA catheter taught by Kontos is one 'interventional cardiology device,' not two."); Ex. 1401, 4:63–5:2 (describing the forces in play "when a physician attempts to direct a guidewire or other interventional cardiology device past an occlusive or stenotic lesion in the branch artery"). And because a "guidewire" and "balloon catheter" are each an interventional cardiology device, as a matter of logic and grammar, to the extent both a "guidewire" and a "balloon catheter" are insertable through the cross-sectional inner diameter of the coaxial lumen, the lumen is sized to accept "interventional cardiology devices."

As noted by Patent Owner, the '380 patent indicates in the "Summary of the Invention" section that the "invention has an inner

diameter that is appropriate for delivering standard coronary treatment devices after it is placed in the blood vessel." Ex. 1401, 5:33–36; PO Resp. 11. The same section clarifies, however, that this is only a preference, not a requirement. Ex. 1401, 3:24–27 ("In addition, the coaxial guide catheter *preferably* has an inner diameter that is appropriate for delivering standard coronary treatment devices after it is placed in the coronary artery.") (emphasis added). In addition, Petitioner persuasively explains why the terms "standard coronary treatment devices" and "interventional cardiology devices" are not co-extensive in scope. Pet. Reply 2.

In view of the foregoing, we determine that use of the term "interventional cardiology devices" in claims 1 and 12 requires that the coaxial lumen of a device has a cross-sectional inner diameter through which at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents and stent catheters, are insertable. For example, the cross-sectional diameter of the lumen may be sized to receive a guidewire and a stent or a balloon. Ex. 1401, 7:60–64 ("Once the guidewire 64 is pushed past stenotic lesion 66 or occlusive lesion (not shown), a treating catheter including a stent or balloon can be passed along the guidewire to stenotic lesion 66 or occlusive lesion (not shown).").[7]

[7] Although we construe claims 1 and 12 to require that the coaxial lumen of the tip portion is sized such that two different types of "interventional cardiology devices" are insertable, Petitioner's construction requiring that only one type of device (e.g., "stents") be insertable through the coaxial lumen is not without support. Ex. 1401, 5:2–5 ("This discussion will refer to a guide wire but it is to be understood that similar principles apply to other interventional cardiology devices including balloon catheters and stent catheters."); Pet. 13, 27–29; Pet. Reply 1. We need not resolve this issue, however, because we find that at least two different types of interventional

D. Claims 1–4, 6, 7, 9, 12–17, 19, and 20 over Kontos and Adams

Petitioner contends the subject matter of claims 1–4, 6, 7, 9, 12–17, 19, and 20 would have been obvious over the combined disclosures of Kontos and Adams. Pet. 17–71.

1. Kontos

Kontos is directed to a support catheter assembly for facilitating medical procedures and, in particular, to a catheter assembly that has "particular utility in facilitating insertion of a PTCA[8] balloon into a lesion." Ex. 1409, 1:9–13.

Figure 1 of Kontos is reproduced below:

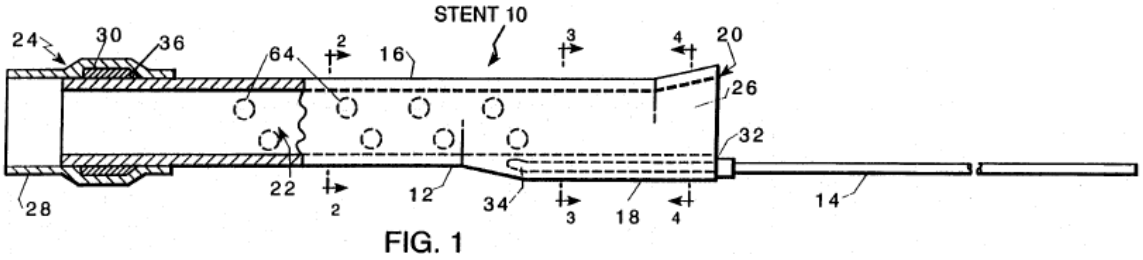


FIG. 1

Figure 1 is a side plan view of a support catheter, "cut-away in part to show in longitudinal cross-section a tubular body having a soft tip and radiopaque marker, and a manipulating wire." Ex. 1409, 2:51–54. As shown in Figure 1, support catheter assembly 10 is composed of two major elements, body 12 and insertion/manipulation wire 14. *Id.* at 3:45–46. Body 12, "which may be viewed as a mini guide catheter, includes tube 16 having a base portion 18 at its proximal end 20." *Id.* at 3:47–49. "Tube 16 has a

---

cardiology devices are insertable through the lumen of Kontos's stent 10, and therefore Kontos teaches this limitation under Petitioner's construction as well.

[8] PTCA stands for "percutaneous transluminal coronary angioplasty." Ex. 1405 ¶ 37.

continuous lumen 22 there through from proximal end 20 to distal end 24." *Id.* at 3:49–50. Body 12 also includes a soft tip 28 disposed at distal end 24 and funnel portion 26 disposed at proximal end 20. *Id.* at 3:50–52. Insertion/manipulation wire 14 is attached to body 12 at base portion 18. *Id.* at 3:52–53. Support assembly 10 may also include distal marker band 30 and proximal marker band 32. *Id.* at 3:53–55.

Kontos explains that the size and shape of the various elements of support assembly 10 "may vary depending on the desired application," but in the embodiment depicted in Figure 1 tube 16 has a 0.055-inch outer diameter and lumen 22 has a 0.045-inch inner diameter. *Id.* at 4:46–50. According to Kontos, the sizes used in these embodiments "are generally suitable for existing PTCA catheters." *Id.* at 4:61–64.

Figure 5 of Kontos is reproduced below:

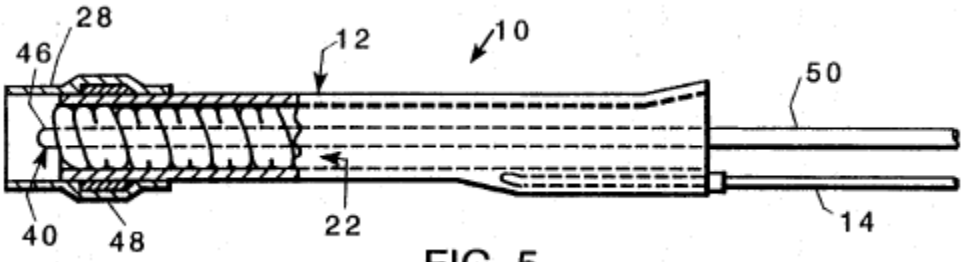
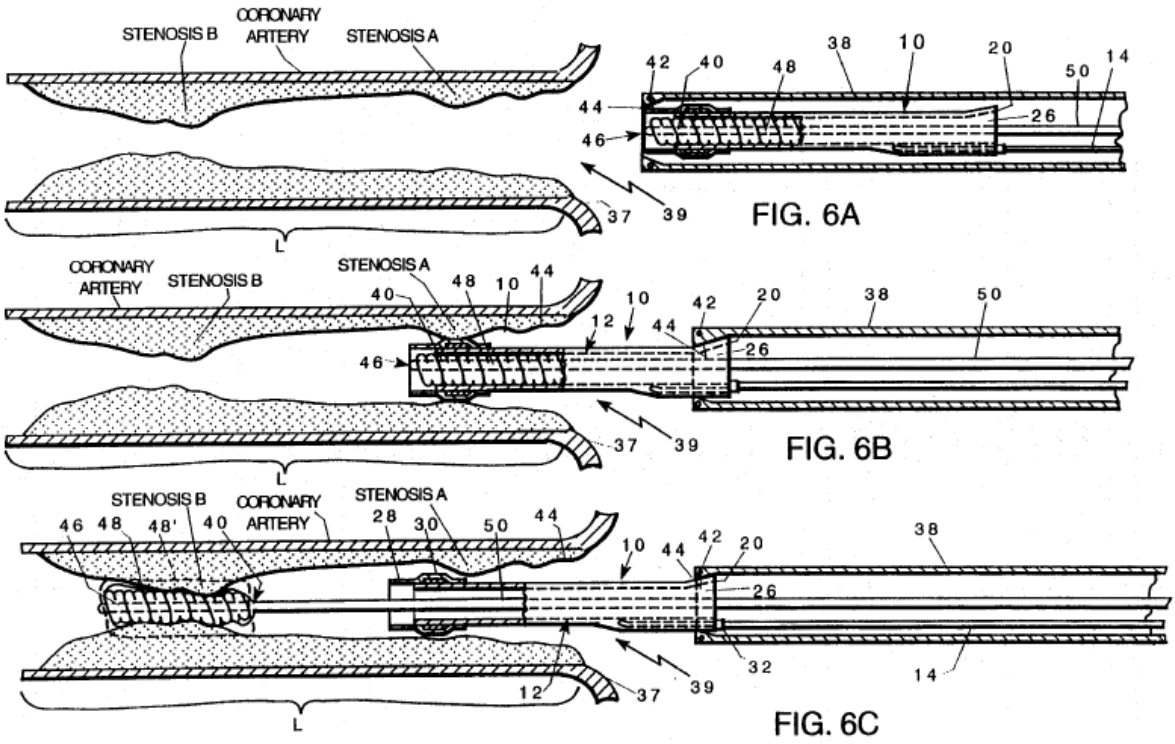


FIG. 5

Figure 5 is a side schematic view of a support catheter having a PTCA catheter disposed therein. *Id.* at 2:64–66. In this figure, PTCA catheter 40 and its deflated balloon 48 reside in lumen 22 of support assembly 10. *Id.* at 5:2–5.

Figures 6A–6C of Kontos are reproduced below:



Figures 6A–6C are cross-sectional views showing three stages in a process for guiding a PTCA catheter to a coronary artery lesion. *Id.* at 2:67–3:2. As shown in Figure 6A, the PTCA catheter/support catheter assembly is first fed into guide catheter 38 and advanced to the distal end of this catheter by exerting axial force on wire 14 and catheter tube 50 simultaneously. *Id.* at 5:25–30.

As shown in Figure 6B, when the PTCA catheter/support catheter assembly reaches the distal end of guide catheter 38, "it may be advanced as a unit out of the distal end of guide catheter 38 and into coronary ostia 39." *Id.* at 5:31–35. When extending beyond the distal end of guide catheter 38, body 12 functions as a guide catheter extension protecting fragile balloon 48 and lessening "considerably the tendency of the PTCA catheter 40 to bend, buckle or kink." *Id.* at 5:52–56. "To help ensure that proximal end 20 does

not unintentionally exit from the guide catheter," guide catheter 38 may be provided with "a radially inwardly formed annular ridge 44 for impeding further axial movement of funnel 26 beyond the distal end of guide catheter 38." *Id.* at 5:59–6:2.

As shown in Figure 6C, after body 12 has been positioned adjacent the restricted area, PTCA catheter 40 is advanced so that balloon 48 exits body 12 and is advanced into the restricted area, e.g., stenosis B. *Id.* at 6:9–13. Balloon 48 is then inflated, as represented by dotted lines 48, "to effect a well-known angioplasty procedure." *Id.* at 6:13–15. Balloon 48 is then deflated and PTCA catheter 40, support catheter assembly 10, and guiding catheter 38 may be withdrawn. *Id.* at 6:15–18.

Although the Figures depict the use of a PTCA catheter, Kontos discloses that, "[o]f course, the device of the present invention may be used with almost any type of catheter, including over-the-wire catheters as well as catheters with captive guide wires." *Id.* at 9:47–50.

2. Adams

Adams discloses a device and method for treating vascular disease. Ex. 1435 ¶ 1. In particular, Adams discloses a device that "includes a distal protection device which is deployed to filter or remove embolic debris" and a device that "creates a seal to prevent the flow of blood during the treatment of vascular disease." *Id.* ¶ 11.

Figure 1A of Adams is reproduced below:

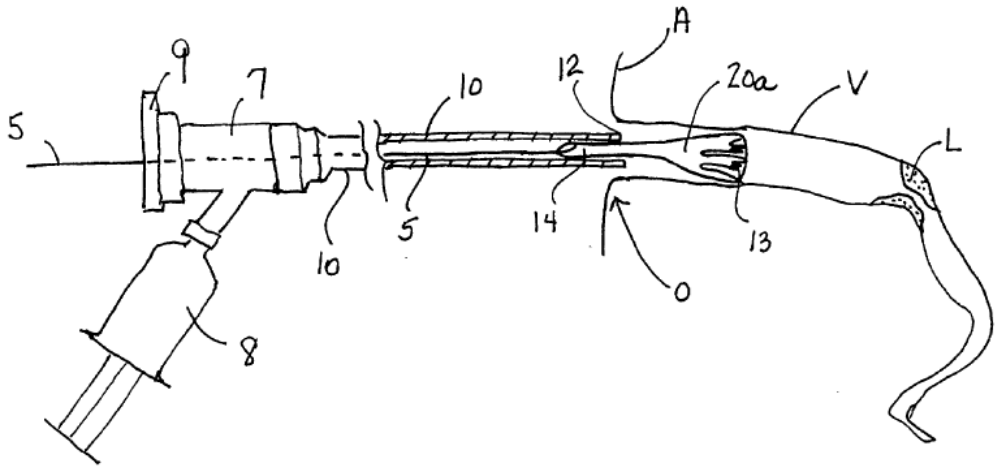


FIG. 1A

Figure 1A is a side view in partial cross-section of the device of Adams. *Id.* ¶ 28. In this figure, Y connector 7 is attached to the proximal end of guide catheter 10 and control wire 5 passes through Y connector 7. *Id.* ¶¶ 59–60. To reduce blood loss, Y connector 7 has hemostasis valve 9 at its proximal end. *Id.* ¶ 60. As shown in Figure 1A, distal end 12 of guide catheter 10 may be inserted into the ostium "O" of coronary vessel "V," which has a lesion "L." *Id.* ¶ 59. Guide seal 20*a* is then deployed beyond the distal end of guide catheter 10. *Id.*

Adams explains that in practice, a physician advances a guidewire through the femoral artery into the aorta. *Id.* ¶ 61. "The guide catheter is then advanced over the guidewire until the distal tip of the guide catheter is in the ostium of the vessel." *Id.* The guide seal is then advanced beyond the distal tip of the guide catheter and, after some additional steps, an embolic protection device of choice may be advanced through the lumen of the guide seal and across the lesion to a point distal to the treatment site. *Id.*

3. Independent Claims 1 and 12

Petitioner identifies where it contends every limitation of independent claims 1 and 12 is taught or suggested in Kontos and Adams. Pet. 17–43, 57–66. In particular, Petitioner contends that: (1) guide catheter 38 of Kontos serves as a "guide catheter" that is adapted to be placed in a branch artery, has a continuous lumen that extends from a proximal end at a hemostatic valve to a distal end that is adapted to be placed in a branch artery, and has a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter (*id.* at 23–29, 57–58); (2) support catheter assembly 10, having body 12 and insertion/manipulation wire 14, is adapted for use with guide catheter 38 (*id.* at 29, 58); (3) body 12 of support catheter assembly 10 is a flexible tip portion defining a tubular structure with a circular cross-section and length that is shorter than the continuous lumen of guide catheter 38 (*id.* at 29–30, 58–60); (4) the cross-sectional outer diameter of body 12 is sized to be insertable through the continuous lumen of guide catheter 38 (*id.* at 30–31, 58–60); (5) tube 16 of body 12 defines a coaxial lumen having a cross sectional inner diameter through which interventional cardiology devices (PTCA catheter 40 with balloon 48) are insertable (*id.* at 31, 60–61); (6) the part of tube 16 that is co-extensive with receiving hole 34 is a "reinforced portion proximal to the flexible tip portion" (*id.* at 32–33, 38–39, 61–62) (7) insertion/manipulation wire 14 defines a rail structure without a lumen and constitutes a substantially rigid portion that is proximal of and operably connected to the flexible tip portion (*id.* at 32–34, 61–62); (8) insertion/manipulation wire 14 has a smaller cross-sectional diameter (0.020 inches) than the outer diameter of tube 16 of

Kontos (0.055 inches) (*id.* at 34); and (9) the combined length of body 12 and insertion/manipulation wire 14 are such that one of ordinary skill in the art would understand the two elements are, in combination, longer than guide catheter 38, such that when body 12 is extended distally of the distal end of guide catheter 38 at least a portion of proximal portion of insertion/manipulation wire 14 extends proximally through the hemostatic valve in common with interventional cardiology devices (PTCA catheter 40) that are insertable into the guide catheter (*id.* at 34–35, 62–67).

To the extent that Kontos does not expressly teach or suggest both a support catheter that has a total length (flexible tip and substantially rigid portion) that is longer than the length of the continuous lumen of the guide catheter, and a proximal end that extends through a hemostatic valve in common with interventional cardiology devices, Petitioner asserts that one of ordinary skill in the art would have found both limitations obvious. Pet. 34. Petitioner reasons that in order for the physician to treat a stenosis using the device of Kontos the combined length of the support catheter must be longer than the length of the guide catheter and the proximal end must extend through a hemostatic valve. *Id.* at 34–36, 57.

To the extent these structural limitations would not have been obvious over Kontos individually, Petitioner contends they would have been obvious in view of the additional disclosures of Adams, which discloses a device having a flexible tip portion and substantially rigid portion with a combined length that is "greater than that of the guide catheter" and that "extend proximal to the hemostatic valve 9 when the guide seal extends beyond the distal end of guide catheter 10." Pet. 36–37, 62–67 (citing Ex. 1435 ¶ 60, Figs. A–B). Petitioner contends one of ordinary skill in the art would have

sought to use the well-known aspects of interventional cardiology devices disclosed in Adams, such as relative sizes and designs, because Kontos teaches that its catheter applies "known medical procedures." *Id.* at 37 (citing Ex. 1409, 5:11–15; Ex. 1405 ¶ 175).

Patent Owner does not contest that one of ordinary skill in the art would have combined the identified disclosures of Kontos and Adams, but contends that Petitioner's arguments with respect to claims 1 and 12 still fail because (1) Petitioner has not demonstrated that at least two devices (or all four under Patent Owner's construction of "interventional cardiology devices") from the group that includes guidewires, balloon catheters, stents, and stent catheters are insertable into the lumen of Kontos's support catheter, and (2) Petitioner has not demonstrated that Kontos discloses a tubular structure that includes a "flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion." PO Resp. 19–24. We address these arguments below.

a) "defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable"

(1) *The Parties' Arguments*

Petitioner contends that lumen 22 of Kontos's catheter has a cross-sectional inner diameter that is sized to allow an interventional cardiology device, such as a PTCA catheter 40 with balloon 48, to be inserted into and travel through tube 16. Pet. 31 (citing Ex. 1405 ¶ 171; Ex. 1409, 4:66–5:2, Figs. 6A–C).

Patent Owner contends that Petitioner's arguments fail because it does not demonstrate that at least two (or all four) of the interventional cardiology devices enumerated in the '380 patent are insertable through the coaxial

lumen of Kontos. PO Resp. 20–21. Patent Owner reasons that the PTCA catheter is a single device having an integrated balloon, and not a balloon catheter and a separable balloon. *Id.* at 22.

Petitioner argues in reply that the 0.045 inch inner diameter of support catheter 10 of Kontos is in fact sized to allow a PTCA catheter, a guidewire, a stent, and a stent catheter to travel through Kontos's body 12. Pet. Reply 4–5 (citing Ex. 1409, 4:46–50; Ex. 1806 ¶¶ 152–158; Ex. 2138 ¶ 48; Ex. 1415, 85; Ex. 1802, 6–7, 15, 21, 25; Ex. 2116, 335:18–336:1).

Patent Owner contends Petitioner's reply arguments regarding guidewires, stents, and stent catheters are untimely, improper, and prejudice Patent Owner's due process rights to fairly respond. Sur-Reply 7–8. Patent Owner further contends that, in the 2005–2006 timeframe, the stents identified by Petitioner still required a minimum guiding catheter diameter of 5 French, which is far larger than the 0.045 inch inner diameter of support assembly 10. *Id.* at 8.

(2) *Analysis*

Kontos discloses a PTCA catheter that is insertable into the lumen of tube 16, and the evidence presented by both Petitioner and Patent Owner persuasively demonstrates that a guidewire will necessarily pass through the 0.045 inch lumen of Kontos's tube 16. Pet. 31; Pet. Reply 4 (citing Ex. 2138 ¶ 48 (Mr. Keith explaining that guidewires are typically 0.014 inches in diameter); Ex. 1806 ¶¶ 153–154). Thus, Petitioner persuasively demonstrates that "interventional cardiology devices" (i.e., both a PTCA catheter and a guidewire) are insertable through the cross-sectional inner diameter of Kontos's tube 16.

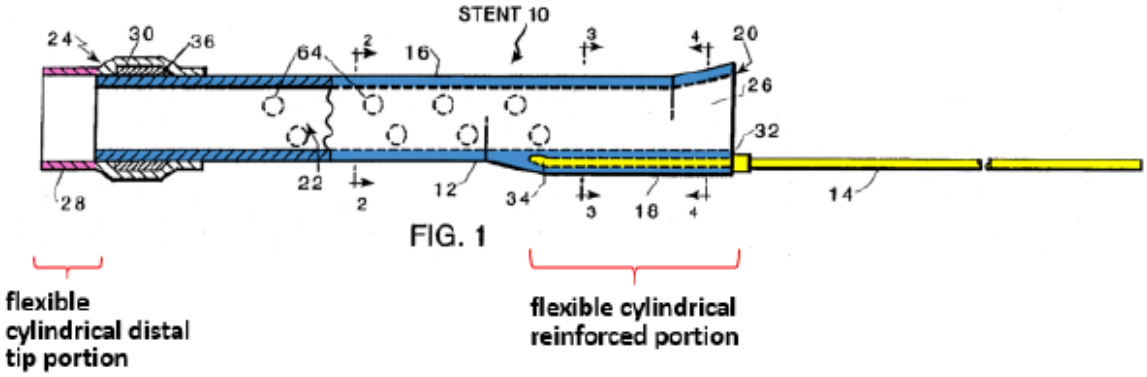
We find that Petitioner's reply arguments regarding guidewires are permissible for at least two reasons. First, Petitioner continues to rely on the same structure of Kontos as meeting the disputed claim limitation, and simply points to evidence and information that was in the record prior to the filing of its Reply to show that this structure satisfies the identified claim language even under the Board's more restrictive construction of "interventional cardiology devices." *See* Pet. 31; Pet. Reply 4; PO Resp. 13 (Patent Owner explaining that the inner diameter of Kontos's tube 16 is 0.045 inches), 31 (asserting that the balloon catheter of Kontos has a "guidewire-like tip"); Ex. 2138 ¶ 48 (Mr. Keith explaining that the diameter of a typical guidewire used in coronary applications is 0.014 inches); *see also* Ex. 1409, 9:47–50 (Kontos explaining that, "[o]f course, the device of the present invention may be used with almost any type of catheter, including over-the-wire catheters as well as catheters with captive guide wires."). Second, although Patent Owner was given an opportunity in the Sur-Reply to generally counter Petitioner's argument that a guidewire is insertable through the inner diameter of Kontos's lumen, Patent Owner did not take advantage of that opportunity. *See Genzyme Therapeutic Prods. Ltd. P'ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1367–69 (Fed. Cir. 2016) (explaining that it is sufficient that a Patent Owner is given notice of reply arguments and an opportunity to respond to them).

b) "flexible cylindrical reinforced portion"

(1) *The Parties' Arguments*

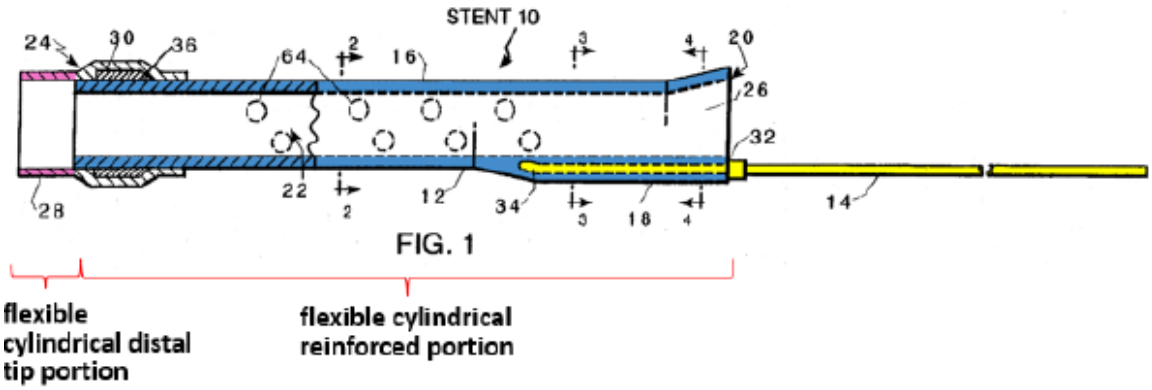
Claim 1 requires a "flexible tip portion defining a tubular structure" that "includes a . . . flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion." Ex. 1401, 10:58, 11:19–22.

Petitioner contends that body 12 of Kontos constitutes a "flexible tip portion defining a tubular structure" and, as shown in the following annotated version of Figure 1 of Kontos, is composed of a "flexible cylindrical distal tip portion" and a "flexible cylindrical reinforced portion."



According to Petitioner, the annotated version of Figure 1 above shows the portions of Kontos that the Petition identifies as the claimed "flexible cylindrical distal tip portion" and the claimed "flexible cylindrical reinforced portion." Pet. 40–41.

Petitioner further argues that one of ordinary skill in the art would have found it obvious to reinforce tube 16 with metallic braiding/coiling, as disclosed in Adams. *Id.* at 42–43. The following annotated version of Figure 1 of Kontos shows where Petitioner identifies the "flexible cylindrical reinforced portion" in this combination (*id.*).



According to Petitioner, the annotated version of Figure 1 above identifies flexible tip portion 28 as the "flexible cylindrical distal tip portion" and the remaining portion of stent 10 (body 12) as the "flexible reinforced portion." *Id.* at 43.

Patent Owner argues that the plain meaning of "cylindrical" is "shaped like a cylinder," and what the Petition points to in Kontos "is not a 'cylindrical' shape." PO Resp. 22–23. Instead, according to Patent Owner, body 12 of Kontos is irregularly shaped, with protruding funnel portion 26 and base portion 18 that tapers inward where the reinforcing pushwire ends. *Id.* at 23–24.

Petitioner argues in response that nothing in the patent requires *perfect* cyclindricality and, as shown in a further annotated version of Figure 1 reproduced below, under either parties' understanding of this claim term Kontos teaches two different flexible cylindrical reinforced portions. Pet. Reply 5–6 (citing Pet. 40–43).

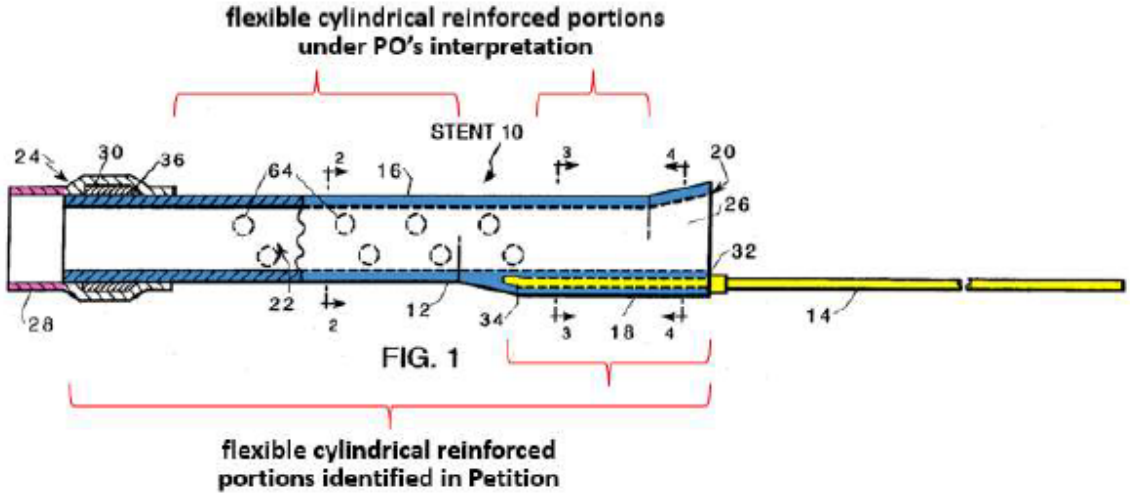


FIG. 1

According to Petitioner, the annotated Figure above shows the identified "flexible reinforced portions" set forth in the Petition and the Reply. *Id.*

Patent Owner argues in its Sur-Reply that although cylindricality need not be absolute, it does not include a structure with "distinctly asymmetric and outwardly protruding structures." Sur-Reply 9. Patent Owner further argues that Petitioner's new mapping of the identified claim language to cover only portions of body 12 of Kontos "is improper and the Board should disregard it." *Id.* at 10.

(2) *Analysis*

Petitioner demonstrates, and Patent Owner does not dispute, that the portions of Kontos's body 12 identified in Petitioner's Reply are proximal to the flexible cylindrical distal tip portion and represent "cylindrical reinforced portions" even under Patent Owner's understanding of claim 1. Sur-Reply 10. Thus, Petitioner persuasively demonstrates that Kontos discloses this claim limitation.

Petitioner's reply arguments are permissible because they merely note that under either parties' understanding of the scope of claim 1, Kontos's

body 12—the structure identified in the Petition—meets the claim limitation in question. *See Apple Inc. v. Andrea Elects. Corp.*, 949 F.3d 697, 706–07 (Fed. Cir. 2020) (rejecting an argument that reply evidence was improper when the "reply does not cite any new evidence or 'unidentified portions' of the [prior art] reference").

c) Conclusion with Respect to Independent Claims 1 and 12

Petitioner persuasively identifies where every limitation of claims 1 and 12 is disclosed in Kontos and Adams. Petitioner also persuasively explains why one of ordinary skill in the art would have combined Kontos and Adams to arrive at the subject matter of claims 1 and 12 with a reasonable expectation of success. Pet. 26, 37–38 (citing Ex. 1405 ¶¶ 163, 174–176). Accordingly, Petitioner demonstrates by a preponderance of the evidence that claims 1 and 12 would have been obvious over Kontos and Adams.

4. Dependent Claims 2 and 13

Claims 2 and 13 depend from claims 1 and 12 respectively and further require that the device include a tubular structure that will, when its distal portion is extended beyond the distal end of the guide catheter, "assist in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery." Ex. 1401, 11:25–32, 12:49–56.

Petitioner contends that claims 2 and 13 recite an intended use that should be afforded no patentable weight. Pet. 44 n.15 (citing *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997)). To the extent that the relevant claim language is limiting, however, Petitioner contends the

extension catheter within the guide catheter provides "stiffer backup support" than a guide catheter alone, and when both the guide catheter and the extension catheter are inserted into a coronary ostium this will improve distal anchoring of the system. *Id.* at 44–45 (citing Ex. 1401, 5:6–27, 8:18–32, Abstr.; Ex. 1405 ¶¶ 191, 198–199).

Patent Owner argues that the functional limitations of claims 2 and 13 may not be ignored and that Petitioner fails to demonstrate that Kontos's protective extension catheter would necessarily provide the resistance to axial and shear forces recited in claims 2 and 13. PO Resp. 24–26. According to Patent Owner, the length and type of materials used in Kontos make body 12 "more akin to a 'wet noodle'" that one of ordinary skill in the art would not expect to provide any reinforcement in the central, narrow portion of tube 16. *Id*. at 26–27. Given these characteristics, Patent Owner posits that if Kontos's extension catheter were subject to backout force it may "rotate, bend, or 'crunch up,' risking damage to the PTCA balloon catheter and injury to the patient." *Id*. at 27–28 (citing Ex. 2138 ¶¶ 151–153; Ex. 2145 ¶ 147).

We agree with Patent Owner that the disputed claim language is a limitation and that this functional language requires a structure that "assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery." *See K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363–64 (Fed. Cir. 1999) (noting that all limitations of a claim must be given weight and that functional language may inform as to structural requirements of the claim). Petitioner and Drs. Jones and Brecker present persuasive evidence, however, that the

device of Kontos will resist axial and shear forces, at least to some extent, when extended into the ostium of a blood vessel. Pet. 45 (citing Ex. 1405 ¶¶ 191, 198–199); Pet. Reply 8–10; Ex. 1806 ¶¶ 159–167; Ex. 1807 ¶¶ 14–27, 152–158 (Dr. Jones testifying the structure and method of use of Kontos's device would necessarily provide some level of backup support). As such, Petitioner demonstrates that the subject matter of claims 2 and 13 is disclosed in Kontos.

We have considered Patent Owner's argument about damage to the PTCA catheter or the patient if Kontos is subjected to backout force, but note that the claims do not require a particular amount of "assist[ance]"[9] or that the device resist axial and shear forces in an efficient manner. Pet. Reply 11. Thus, that Kontos may perform the "assist" function poorly as compared to the claimed device is not pertinent to our analysis as to whether Kontos discloses that feature of the claims.

In view of the foregoing, Petitioner demonstrates by a preponderance of the evidence that claims 2 and 13 would have been obvious over the combined disclosures of Kontos and Adams.

5. Dependent Claims 6, 7, 15–17, and 20

Petitioner presents persuasive argument and evidence that Kontos and Adams teach or suggest the subject matter of claims 6, 7, 15–17, and 20. In particular, Petitioner demonstrates that: (1) Adams discloses using

[9] Claims 2 and 13 state that the device assists in resisting axial and shear forces that "would otherwise tend to dislodge the guide catheter from the branch artery." Patent Owner does not assert in its Response or Sur-Reply that this portion of the claim requires a particular quantum of assistance in resisting axial or shear forces. PO Resp. 26; Sur-Reply 11.

metallic elements in a braided or coiled pattern to reinforce portions of the catheter, as recited in claims 6 and 17 (Pet. 53–54, 69 (citing Ex. 1435 ¶¶ 49, 66, Fig. 3A); Ex. 1405 ¶ 217); (2) Kontos discloses using a radiopaque marker in a flexible cylindrical distal tip portion that is proximate to the distal tip, as recited in claim 7 (*id.* at 54 (citing Ex. 1409, 4:19–21; Ex. 1405 ¶ 218)); (3) Kontos discloses a device wherein an interventional cardiology device may be inserted while utilizing a single hemostatic valve and without the use of any telescoping structure, as recited in claim 15 (*id.* at 68–69 (citing Ex. 1409, 7:45–52; Ex. 1405 ¶ 237)); (4) Kontos discloses a radiopaque marker proximate to the distal portion of the flexible tip portion, as recited in claim 16 (*id.* at 69 (citing Ex. 1409, Fig. 1; Ex. 1405 ¶ 238)); and (5) Kontos teaches or suggests a second flexural modulus that is greater than a first flexural modulus and a third flexural modulus that is greater than the second flexural modulus, as recited in claim 20 (*id.* at 70–71 (citing Ex. 1405 ¶¶ 136–137, 242; Ex. 1442 ¶¶ 64–68)).

Patent Owner does not directly address Petitioner's arguments and supporting evidence with respect to claims 6, 7, 15–17, and 20 of the '380 patent. *See generally* PO Resp. 19–44.

Upon review of Petitioner's arguments and evidence, we find that Petitioner adequately shows where Kontos and Adams disclose every limitation of claims 6, 7, 15–17, and 20. We further find that Petitioner persuasively explains why one of ordinary skill in the art would have combined the identified disclosures of Kontos and Adams to arrive at the claimed subject matter. Accordingly, Petitioner demonstrates by a preponderance of the evidence that claims 6, 7, 15–17, and 20 are unpatentable as having been obvious over Kontos and Adams.

6. Dependent Claims 3, 4, 9, 14, and 19

a) The Parties' Arguments

Claim 3 depends from claim 2 and requires that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter." Ex. 1401, 11:33–40. Claims 4, 9, 14, and 19, likewise require a side opening (or elements resulting in a side opening). *Id.* at 11:41–43, 11:58–61, 12:57–65, 13:18–21.

Petitioner concedes that Kontos does not teach or suggest a side opening extending for a distance along the longitudinal axis, but contends such structures were well known in the art and are disclosed in Adams. Pet. 47, 55–57, 67–68, 70 (citing Ex. 1405 ¶¶ 95–108, 202, 205–207, 223, 236, 241; Ex. 1442 ¶ 100; Ex. 1407, 4:15; Ex 1408, 12:9–13:60, Fig. 6A–6E; Ex. 1418, Fig. 7; Ex. 1432, 119, Fig. 1; Ex. 1433 ¶¶ 35, 49, Fig. 2; Ex. 1435 ¶ 66; Ex 1450, Fig.7; Ex. 1461, 6:9–11, Fig. 1B). Petitioner asserts that one of ordinary skill in the art would have sought to modify Kontos to add a side opening at the proximal end of tube 16, as taught by Adams, for multiple reasons. First, Petitioner contends use of a proximal opening would allow for reduction of the outer diameter of the catheter assembly without a commensurate reduction in the area for the point of entry of the extension catheter. Pet. 48–49 (citing Ex. 1405 ¶ 205; Ex. 1442 ¶ 100). Second, Petitioner contends a proximal side opening would facilitate a "smoother" reception of the interventional cardiology device as it enters the lumen of the

child catheter. *Id.* at 50 (citing Ex. 1408, 6:52–57; Ex. 1405 ¶¶ 208–210; Ex. 1442 ¶¶ 101–102; Ex. 1426, 3:6–9). Third, Petitioner contends a person of ordinary skill in the art would understand that a side opening would reduce the force a physician would need to exert to advance the catheter through tortuous vasculature. *Id.* at 50–51 (citing Ex. 1408, 6:52–57; Ex. 1405 ¶ 211; Ex. 1442 ¶ 103; Ex. 1425, Abstr., ¶ 34). Fourth, Petitioner contends a person of ordinary skill in the art would understand that a proximal side opening would permit smooth re-entry if the proximal end of the extension catheter was extended beyond the distal end of the guide catheter. *Id.* at 51–52 (citing Ex. 1405 ¶¶ 212–214; Ex. 1442 ¶¶ 97–99).

Patent Owner contends one of ordinary skill in the art would not have made the proposed modifications to Kontos's device for multiple reasons. First, Patent Owner argues that protruding base portion 18 and larger diameter tip portion 28 create a substantial gap between the device and the inner wall of the guide catheter, which Kontos addresses by using funnel portion 26. PO Resp. 29. According to Patent Owner, removing funnel portion 26 would make the device "worse" by exposing the gap and greatly increasing the likelihood of catching or hang-up when a device is inserted through the catheter. *Id.* at 30–32 (citing Ex. 2138 ¶¶ 160–163; Ex. 2145 ¶¶ 214–217; Ex. 2137, 345:19–346:6).

Second, Patent Owner argues that side openings to receive an interventional cardiology device when a device is positioned within a guide catheter were "very rare" in the art and the proximal end of Adams is only used to facilitate the collapse of the mesh when it is back-loaded into the distal end of the guide catheter, not to facilitate entry of a device at the proximal opening. *Id.* at 32–36 (citing Ex. 1435 ¶61; Ex. 2138 ¶¶ 165–175;

Ex. 2145 ¶¶ 107–109) (asserting that only Ressemann discloses a side opening to receive an interventional cardiology device). Indeed, Patent Owner contends Adams teaches removing mesh guide seal 20 prior to advancing a treatment device to the treatment site. *Id.* at 35 (citing Ex. 1435 ¶ 64).

Third, with respect to the purported benefit of reduced size when the funnel portion of Kontos is removed, Patent Owner argues that no size benefit would be obtained from this modification because the distal tip marker band and protruding base portion 18 would still set the outer diameter of the device, thereby preventing any decrease in size. PO Resp. 37–38. In addition, Patent Owner notes that Kontos is already sized consistently with usage in a 6 French guide catheter and, in the relevant time frame, smaller catheters were not routinely used in the art and offered no major advantage. *Id.* at 38–39 (citing Ex. 2167, 33; Ex. 2145 ¶ 220).

Fourth, Patent Owner contends that Petitioner's argument that a side opening would allow for smoother passage of the catheter assembly through tortuous vasculature is simply unsupported by the evidence of record, as it is the distal end of the catheter that drives the ease of advancement. *Id.* at 40 (citing Ex. 2138 ¶¶ 188–189; Ex. 2145 ¶ 223).

Finally, Patent Owner argues that the fourth proposed motivation of permitting "smooth reentry" if the catheter were pushed entirely out of the end of the guide catheter is based on hindsight and generally contrary to what Kontos teaches. *Id.* at 41. According to Patent Owner, Kontos instructs that it is generally not desirable to extend the proximal end of body 12 beyond the distal end of the guide catheter, and all experts agree that a person of ordinary skill in the art would "never" have actually done

this. *Id.* (citing Ex. 1409, 5:67–6:2, 6:23–28, Fig. 6B; Ex. 2116, 365:14–25, 366:22–367:5; Ex. 2137, 329:4–9; Ex. 2138 ¶¶ 109, 124, 190–191; Ex. 2145 ¶¶ 149, 224).

Petitioner argues in reply that removing the funnel of Kontos and increasing the diameter of the catheter would maximize real estate within the catheter, which was universally understood to be advantageous. Pet. Reply 12–15. Petitioner further argues that raised marker band 30 could be recessed or embedded in the catheter, obviating the need for a raised profile. *Id.* at 15 (citing Ex. 1807 ¶¶ 168–182). With respect to the argument that removal of the funnel would lead to devices catching during entry into the catheter, Petitioner argues that the dimensions of Kontos demonstrate that this concern is incorrect. *Id.* at 18. According to Petitioner, the gap between the outer diameter of tube 16 and the inner diameter of the guide catheter would be 0.005 inches, whereas a guidewire, or "the distal-most wire of a fixed-wire balloon," is typically 0.014 inches in diameter. *Id*. Petitioner contends these size differences demonstrate that a PTCA catheter would not catch in the gap between tube 16 and the inner wall of the guide catheter. *Id.* at 17–18.

Finally, Petitioner argues that Ressemann expressly states that side openings facilitate smoother passage of interventional cardiology devices and that Mr. Keith argued in a prior litigation that the funnel of Kontos contributes to a "pushability problem." *Id.* at 16–17 (citing Ex. 1819 ¶ 112).

In its Sur-Reply, Patent Owner argues that it is now undisputed that even with its funnel removed, Kontos's device is still too large to fit in a 5 French guide catheter, a primary reason set forth in the Petition for making the proposed modification. Sur-Reply 12 (citing Ex. 2241, 107:8–15).

Patent Owner further argues that Petitioner's argument that removal of Kontos's funnel and implementing a side opening would maximize the usable real estate within the guide catheter is a new argument that should not be permitted for the first time in reply. *Id.* at 14.

To the extent Petitioner's new arguments are considered, Patent Owner contends they are nonetheless unpersuasive. Patent Owner reasons that Petitioner provides no explanation as to how the marker bands of Kontos could be recessed and still allow for attachment of soft tip portion 28, a step which there was no obvious way to accomplish in 2005. *Id.* at 15 (citing Ex. 1807 ¶¶ 168–182; Ex. 1800, 194:19–197:24). Petitioner further reasons that redesigning Kontos's device to maximize its interior diameter is contrary to the purpose of the support catheter, which is to protect delicate fixed-wire balloon catheters and still have a small enough profile to fit inside a lesion and act as a temporary stent. *Id.*

b) Analysis of Obviousness Arguments

As set forth above, the Petition provides multiple reasons why one of ordinary skill in the art would have wanted to remove the funnel of Kontos and provide an angled side opening. Patent Owner provides several arguments in response as to why the modifications suggested by Petitioner are grounded in hindsight, including the required, but previously-undescribed, recessing of raised marker band 30.

Upon review of the parties' arguments and supporting evidence, we find the parties' arguments present a close case on the question of obviousness. For example, while side openings were known in the art, they were rare in devices intended to receive an interventional cardiology device when positioned within a guide catheter. Moreover, switching to a side

opening in Kontos to beneficially increase the available real estate within the catheter or to reduce the size of the guide catheter would require several modifications to the device, at least one of which was not mentioned in the Petition and may not have been possible in the relevant time period (recessing marker band 30).

Ultimately, as explained below, we determine that Petitioner has not met its burden for these claims, particularly in view of the objective indicia evidence provided by Patent Owner.

Objective indicia of non-obviousness, or "secondary considerations," guard against hindsight reasoning in an obviousness analysis, and are often "the most probative and cogent evidence in the record." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016) (citations omitted). As such, objective indicia of non-obviousness must be considered in every case in which they are presented. *Id.* (citing *Transocean Offshore Deepwater Drilling Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012)).

Objective indicia of non-obviousness include: (1) commercial success; (2) long-felt but unsolved needs; (3) failure of others; (4) copying; (5) praise in the art; (6) unexpected results; and (7) industry acceptance. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1129 (Fed. Cir. 2000) (citing *Graham*, 383 U.S. at 17; *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1092 (Fed. Cir. 1987)).

As objective indicia relevant to the challenged claims, Patent Owner presents evidence that its GuideLiner products, i.e., GuideLiner V1, GuideLiner V2, and GuideLiner V3, as a whole, solved a long-felt but unresolved need in the art, are commercially successful, were repeatedly

copied by competitors, and received industry praise. PO Resp. 52–69. Patent Owner also presents evidence that the '380 patent was licensed by a competitor. *Id.* at 62. Patent Owner contends this objective evidence of non-obviousness precludes a determination of obviousness with respect to claims 3, 9, 14, and 19. *Id.* at 52.

(1) *Long-Felt Need*

"Evidence of long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would not have persisted had the solution been obvious." *WBIP*, 829 F.3d at 1332. Patent Owner contends that in the late 1980s and early 1990s it was recognized in the interventional cardiology field that there was a tendency for a guide catheter to back out of the ostium if a stent or balloon encountered significant resistance within the coronary vasculature. PO Resp. 52–53. This problem often prevented successful procedures due to the inability to advance the stent or balloon into the lesion needing treatment. Ex. 2145 ¶¶ 41–42; Ex. 2215 ¶¶ 10–19; Ex. 2138 ¶¶ 213–214.

The long-felt need for a product that would not back out of the ostium when a stent or balloon encountered significant resistance is supported by the testimony of Dr. John Graham (Ex. 2145), Dr. Lorenzo Azzalini (Ex. 2151), and Dr. Craig Thompson (Ex. 2215). Each of these doctors has performed thousands of percutaneous coronary interventions, including complex percutaneous coronary interventions, and they unanimously agree that since at least the early 1990s the field struggled with the problem of insufficient guide catheter backup support when seeking to navigate difficult anatomy or crossing difficult lesions. Ex. 2145 ¶¶ 10, 42; Ex. 2215 ¶¶ 2–6; Ex. 2151 ¶¶ 2, 4.

Dr. Graham explains that in this time period there were at least four approaches a physician could use in an attempt to overcome the lack of backup support: a physician could attempt to "deep seat" the guide catheter in the ostium; "upsize" the catheter or change to a stiffer catheter; thread a second guidewire, or "buddy" wire; or use a mother-and-child approach, inserting a smaller, full-length guide catheter into the already-in-place guide catheter. Ex. 2145 ¶ 50. Drs. Graham, Azzalini, and Thompson testifiy that each of these approaches presented significant difficulties related to time, expense, and potential injury to the patient. *Id.* ¶¶ 51–66; Ex. 2215 ¶¶ 9–19; Ex. 2151 ¶¶ 9–14. For example, Dr. Graham testifies that switching to a mother-and-child approach required a longer 300 cm "exchange length" guidewire that is more difficult to manage than the typical 180-200 cm guidewire and requires the assistance of a second operator. Ex. 2145 ¶¶ 62–63. The mother-and-child approach also required "re-crossing a lesion a second time," which Dr. Graham explains is "highly undesirable and potentially dangerous." *Id.* ¶ 63.

Dr. Graham, Dr. Thompson, and Dr. Azzalini agree that the GuideLiner products, with their pushrod structure, distal tubular structure, and side opening located at the junction of the pushrod and tubular structure, overcame the backout problem, allowing for stents and balloons to be delivered deep into the coronary vasculature and allowing physicians to treat patients "who otherwise would have been untreatable with a catheter procedure." Ex. 2215 ¶¶ 22–23; Ex. 2145 ¶ 67 (Dr. Graham testifying that the GuideLiner product "provided a highly effective, reliable solution to the longstanding problem of lack of backup support."); Ex. 2151 ¶ 9 (Dr. Azzalini testifying that the GuideLiner product "changed the field of

interventional cardiology" and gave cardiologists a device "that finally solved the long-existing guide catheter backout problem.").

Petitioner does not generally dispute the impact the GuideLiner products had on the field of interventional cardiology, but contends that Kontos, Itou, and Ressemann all provide backup support, and it was understood in the art that full-length, mother-and-child devices "provide guide extension and additional backup support." Pet. Reply 22–29 (citing Ex. 1800, 26:10–27:8; Ex. 1817, 25:20–26:9, 37:8–38:6). Although Kontos and Ressemann[10] both provide some level of backup support, there is no persuasive evidence that either of these products resolved the long-felt need in the art for a device that would avoid backout problems when difficult lesions are encountered during a procedure. *See* Ex. 2151 ¶¶ 8–9. And although mother-and-child devices were known to provide additional backup support, Patent Owner's declarants persuasively demonstrate that a mother-and-child approach was not a safe or time- and cost-effective solution to the backout problem addressed by the GuideLiner products. PO Resp. 53–55; Ex. 2151 ¶¶ 6–8; Ex. 2145 ¶¶ 60–66; Ex. 2215 ¶¶ 16–19 (Dr. Thompson testifying that the problems related to the mother-and-child approach led to very limited use of this technique). Indeed, in view of its inherent limitations, the mother-and-child approach was rarely, if ever, used by interventional cardiologists. Ex. 2145 ¶ 66 (Dr. Graham testifying that the

[10] For the reasons discussed in IPR2020-00128, we find that Itou is not prior art to claims 1–4, 6–9, and 12–21 of the '380 patent challenged in this proceeding. *See* IPR2020-00128, Paper 127. As such, we do not consider Petitioner's arguments with respect to Itou in our analysis of secondary considerations. Even if we were to consider Itou, however, it would not change our analysis with respect to secondary considerations.

mother-and-child approach "had many significant drawbacks" and he was "not aware of any instances in which a mother-and-child system was successfully marketed."); Ex. 2215 ¶ 16 ("The mother-and-child approach was rarely, if ever, used by interventional cardiologist for a number of reasons.").

In view of the foregoing, we credit the testimony of Drs. Graham, Thompson, and Azzalini and find that the GuideLiner products solved a long-felt but unmet need in the art, allowing physicians to perform previously impossible coronary procedures.

(2) *Commercial Success*

"Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). Petitioner's own internal documents [redacted] and Patent Owner presents uncontroverted evidence that through 2019 it and its licensee (Boston Scientific) "had essentially 100% of the U.S. guide extension catheter market," achieving nearly [redacted] in annual revenue. PO Resp. 56–58 (citing Ex. 2153 ¶¶ 2–8; Ex. 2154); Ex. 2198, 3.

Petitioner does not generally dispute that Patent Owner's GuideLiner products are commercially successful. *See generally* Pet. Reply 22–29.

Upon review of the arguments and the evidence of record, we find that the GuideLiner products achieved a high level of commercial success.

(3) *Industry Praise*

Evidence that the industry praised a claimed invention weighs against an assertion that the same claim would have been obvious because industry participants, especially competitors, are not likely to praise an obvious advance over the known art. *WBIP*, 829 F.3d at 1334.

Published scientific journals and text books praise the properties of the GuideLiner products. For example, a review article in the International Journal of Cardiology states that the GuideLiner product "provides an elegant method to overcome" the problem of "severe vessel angulation and tortuosity" and has "significantly improved procedural outcomes in complex lesion anatomy and broadened the subset of lesions where PCI can be successfully performed." Ex. 2194, 142, 147; PO Resp. 60. A technical report in EuroIntervention reports that GuideLiner allowed a stent to be "easily and successfully" deployed in a case where stent delivery was otherwise "impossible despite the use of a highly supporting guiding catheter." Ex. 2180, 279; PO Resp. 60. In addition, a text book on catheterization procedures notes that "[l]ack of backup support can be easily overcome by using a guide catheter extension such as a Guideliner," which "does not add complexity to the intervention and provides extraordinary backup support for complex interventions." Ex. 2167, 182; PO Resp. 60.

Petitioner does not dispute that Patent Owner's GuideLiner product was praised in the industry. *See generally* Pet. Reply 22–29.

Upon review of the parties' arguments and the evidence of record, we find that the GuideLiner product received significant praise in the industry.

(4) *Licensing*

Evidence that competitors or customers have licensed a patent may provide probative and cogent evidence of non-obviousness of the claims at issue. *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013). Patent Owner presents evidence that its competitor, Boston Scientific, licensed the GuideLiner patents [redacted]. PO Resp. 62 (citing Ex. 2044 ¶ 34; Ex. 2153 ¶ 8). Patent Owner also asserts that Petitioner sought a license to the GuideLiner patent portfolio. *Id.* (citing Ex. 2044 ¶ 21; Ex. 2068 ¶ 26).

Petitioner asserts that Patent Owner's licensing evidence is not persuasive because it has not submitted the Boston Scientific license in this case or provided any context surrounding the license, which was entered into as part of a settlement agreement. Pet. Reply 27 n.7.

The mere existence of a license, without evidence that the license was entered into because of the merits of the claimed invention, is of limited probative value because it is often "cheaper to take a license than to defend infringement suits." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1324 (Fed. Cir. 2004); *In re Antor Media Corp.*, 689 F.3d 1282, 1293–94 (Fed. Cir. 2012) (determining that the existence of licenses was insufficient because the licenses may have been entered into "as a business decision to avoid litigation, because of prior business relationships, or for other economic reasons"). Here, Patent Owner does not explain in any detail the terms of the Boston Scientific license or the circumstances under which the license was granted, except to concede that the license was taken in settlement of litigation. *See* PO Resp. 62; Ex. 2044 ¶ 34. Thus, Patent

Owner's licensing efforts are of limited probative value in this case. *See Iron Grip*, 392 F.3d at 1324.

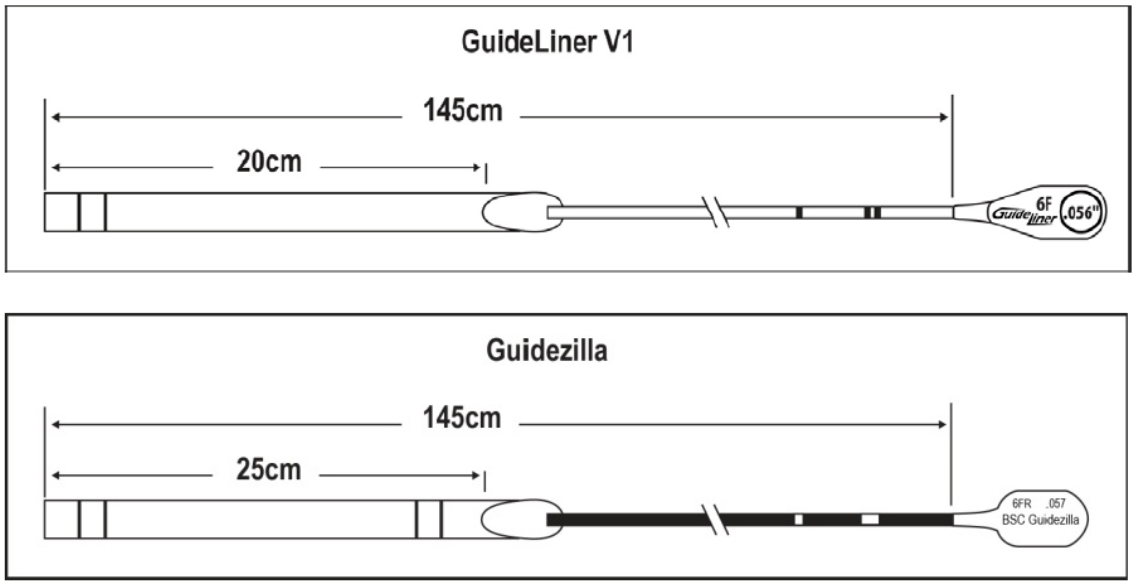
(5) *Copying*

Evidence of copying of the claimed invention by a competitor, rather than one within the public domain, tends to show nonobviousness. *WBIP*, 829 F.3d at 1336. As discussed below, Patent Owner contends its competitors copied the GuideLiner products, whereas Petitioner contends the competing products identified by Patent Owner merely copied what was known in the prior art.

(a) The Parties' Arguments

Patent Owner asserts that after the introduction of the GuideLiner product "three companies launched products that not only infringed the GuideLiner patents but were close copies of then-existing versions of the commercial GuideLiner products." PO Resp. 63. These products are Boston Scientific's "Guidezilla" product, QXMedical's "Boosting Catheter," and Petitioner's "Telescope" product.

Patent Owner contends that Boston Scientific's Guidezilla product is virtually identical to the GuideLiner V1 product. PO Resp. 63. In support of its arguments, Patent Owner provides the following annotated comparison of GuideLiner V1 and the Guidezilla product. *Id*.



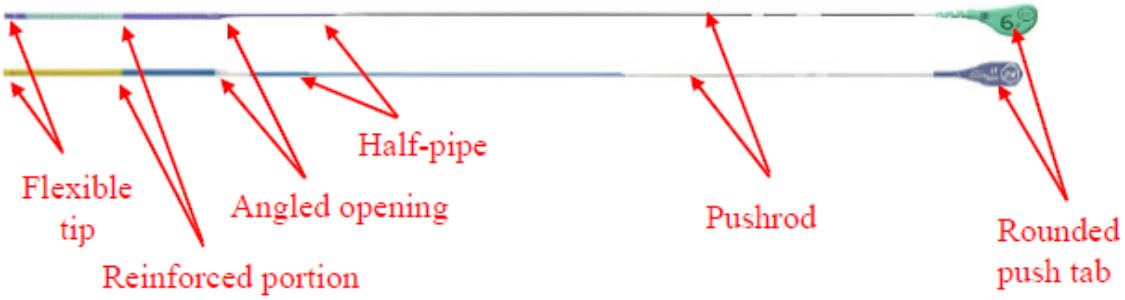
The figure above shows the general structure and length of the GuideLiner V1 and Guidezilla products. Referencing the above figures, Mr. Keith testifies that the two devices both have a flexible tube with a lumen, a rigid collar, a rigid metallic pushrod, and a handle that is marked with the device's size. Ex. 2138 ¶¶ 232–237. When all of the elements of the two devices are considered in combination, Mr. Keith testifies that the two devices are "virtually identical." *Id.* ¶ 238. Dr. Graham likewise testifies that both products are "substantially similar" and that in his clinical experience "Guidezilla functions and performs similarly to GuideLiner." Ex. 2145 ¶¶ 261–263.

Patent Owner contends that Boston Scientific confirmed the substantially similar nature of the two devices in its regulatory filings, informing regulators that Guidezilla "incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use"

as GuideLiner. PO Resp. 64–65 (citing Ex. 2138 ¶¶ 231–249; Ex. 2145 ¶¶ 261–263; Ex. 2151 ¶ 12; Ex. 2046 ¶¶ 68–79; Ex. 2200, 1).

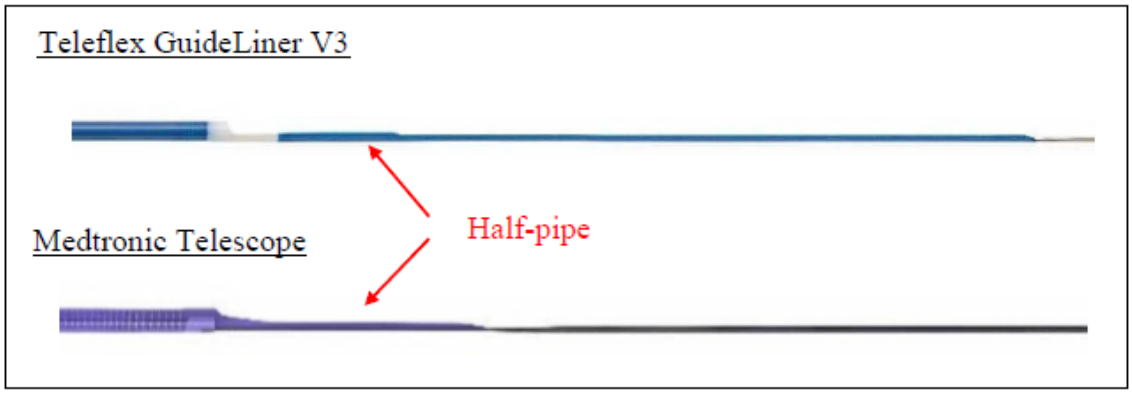
With respect to the "Boosting Catheter," Patent Owner contends that QXMedical had access to the GuideLiner V1 and developed a "substantially similar" product. *Id.* at 65 (citing Ex. 2138 ¶¶ 240–249; Ex. 2196, 1).

With respect to Petitioner's Telescope product, Patent Owner contends [redacted] and, as shown in the annotated figure below, Petitioner's Telescope product is a striking copy of Patent Owner's GuideLiner V3 product. PO Resp. 65, 69.



The figure above is annotated by Patent Owner to identify the alleged similarities between GuideLiner V3 and Petitioner's Telescope product, including a flexible tip, reinforced portion, angled opening, Half-pipe, pushrod, and rounded push tab. *Id.* at 66.

Addressing the product's "Half-pipe" feature, Patent Owner provides the following annotated figure showing the similarities between the half-pipe of GuideLiner V3 and the Telescope product (*id.* at 68).



The figure above is an annotated, side-by-side comparison of the "Half-pipe" of Patent Owner's GuideLiner V3 product and Petitioner's Telescope product. *Id.* Patent Owner contends [redacted] and comparison of the two devices demonstrates that "Petitioner succeeded in its efforts to copy" this feature into its Telescope product. *Id.* at 67–68 (Patent Owner asserting that the two products have very similar side openings and, while not quite as long, Petitioner's half-pipe is "nonetheless quite long and (like GuideLiner V3) includes two inclined regions with a non-inclined region in between"); Ex. 2197, 1[redacted] Ex. 2138 ¶ 256.

Petitioner argues that the elements identified by Patent Owner to establish copying of Guidezilla and the Boosting Catheter are all found in the prior art. Pet. Reply 27. In particular, Petitioner asserts that Guidezilla and the Boosting Catheter are similar to Itou and Ressemann in that they are rapid exchange devices that are "configured to deliver a wide variety of IVCDs and provide increased backup support when extended partially past a [guide catheter]." *Id.* Petitioner further asserts that, "[l]ike Itou and Ressemann, Guidezilla also had a side opening." *Id.*

With respect to its Telescope product, Petitioner contends this product simply "practices the prior art" and "[n]one of the claims for which [Patent Owner] claims nexus in this IPR pertain to its 'half-pipe.'" Pet. Reply 28. In addition, Petitioner contends that Patent Owner "ignores the numerous unclaimed but important differences between GuideLiner and Telescope, including Telescope's hydrophilic coating and round pushwire," differences Patent Owner "itself emphasizes . . . as core distinguishing features" between the two products. *Id.* at 29 (citing Ex. 1824, 4:22–5:10).

(b) Analysis

Evidence of copying may take the form of "internal documents, direct evidence such as photos or patented features, or disassembly of products, or access and similarity to a patented product." *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1137 (Fed. Cir. 2019).

Patent Owner persuasively demonstrates that Guidezilla, the Boosting Catheter, and Petitioner's Telescope product were launched into the market after the relevant GuideLiner products. Thus, each competitor had access to the GuildeLiner products. *See* Ex. 2200, 1; Ex. 2138 ¶ 247; Ex. 2196, 1; Ex. 2202, 1–2. Patent Owner and Mr. Keith also persuasively demonstrate that the Guidezilla and Telescope products,[11] when considered as a whole, are substantially similar in design to the then-existing GuideLiner products on the market, including the combined use of a flexible tip, reinforced

[11] Patent Owner provides no figures or description comparing the Guideliner product to the Boosting Catheter. Although Dr. Keith does provide such a comparison, Patent Owner may not incorporate these materials by reference into its Response. 37 C.F.R. § 42.6(a)(3). As such, we make no findings with respect to the similarity of GuideLiner and the Boosting Catheter in this proceeding.

portion, angled opening, pushrod, and rounded push tab.[12] PO Resp. 63–68; Ex. 2138 ¶¶ 231–239.

As Petitioner notes, Ressemann is a rapid exchange device and has a side opening. But Guidezilla did not merely apply the idea of rapid exchange or the use of a side opening, as the device reproduces the entire combination of features that were assembled for the first time by the GuideLiner products. As such, we do not find persuasive Petitioner's argument that Guidezilla merely copied the prior art, as opposed to the relevant GuideLiner products.

Petitioner's Telescope product differs from GuideLiner V3 in its use of a hydrophilic coating and a round pushwire, and the "half-pipe" design of the two products is not identical. Pet. Reply 28–29. We credit the testimony of Mr. Keith, however, that the overall design of the two products is substantially similar (Ex. 2138 ¶¶ 250–262), and there is little doubt that Petitioner had access to GuideLiner products and [redacted] Ex. 2235, 5 [redacted] 15–17 [redacted] Ex. 2198, 3 [redacted] Ex. 2197,

[12] We note that Boston Scientific has not had the opportunity to refute Patent Owner's "substantial similarity" arguments. We find only that, on this record, Petitioner has not refuted Mr. Keith's testimony that the Guidezilla product, when considered as a whole, is substantially similar to the relevant GuideLiner V1 product. Ex. 2138 ¶¶ 240–249.

1 [redacted] Ex. 2069, 5. As such, the evidence of copying by Petitioner is relevant in this case and favors, at least to some extent, a conclusion of non-obviousness of the claims at issue. *See Liqwd*, 941 F.3d at 1138–39.

(6) *Nexus*

To be relevant, a nexus must be established between the evidence of secondary considerations and the merits of the claimed invention. *Liqwd*, 941 F.3d at 1138. A presumption of nexus exists "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'is the invention disclosed and claimed in the patent.'" *WBIP*, 829 F.3d at 1329 (quoting *J.T. Eaton & Co. v. ATl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997)).

Mr. Keith provides unrebutted claim charts demonstrating that the GuideLiner V1, V2, and V3 products read on every limitation of claims 1, 2, 3, 9, 12, 14, and 19 of the '380 patent. Ex. 2138, Appendix B at 1–37 (Declaration of Peter Keith). Patent Owner also persuasively ties its evidence of long-felt need, commercial success, industry praise, and copying to one or more of the GuideLiner V1, V2, and V3 products. PO Resp. 52–76. Accordingly, a presumption of nexus applies in this case. *Id.* at 69–70; Ex. 2138 ¶¶ 211–212, 263, Appendix B; *WBIP*, 829 F.3d at 1329–30.

The presumption of nexus may be rebutted by showing that the proffered objective evidence was due to extraneous factors other than the patented invention, such as additional unclaimed features or improvements in marketing, etc. *WBIP*, 829 F.3d at 1329. The presumption of nexus may also be rebutted by showing that the objective evidence results from a feature that was known in the prior art. *Id.*; *In re Kao*, 639 F.3d 1057, 1068

(Fed. Cir. 2011) ("where the offered secondary considerations actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention.").

Petitioner argues that other than "the side opening," which was generally known in the art, "Kontos discloses the structure of" claims 3, 9, 14, and 19. Pet. Reply 23. Petitioner further argues that all that is necessary to apply the benefits of modern guide extension catheters is rapid exchange, a side opening, and a lumen relatively close to the size of the guide catheter, and Kontos, Itou, and Ressemann all disclose rapid exchange and a lumen close in size to the guide catheter (providing backup support), and Itou and Ressemann have side openings. *Id*. at 24–27.

As noted by Petitioner, every element of the disputed claims was individually known in the prior art. But evidence of secondary considerations may be tied to the combination of features as a whole, as opposed to one or more "novel" elements of a claimed invention. *See WBIP*, 829 F.3d at 1331–32. In line with this precedent, Drs. Graham, Thompson, and Azzalini persuasively testify that it was the GuideLiner devices as a whole that resulted in the evidence of secondary considerations, not any individual feature in isolation. Ex. 2138 ¶ 215; Ex. 2145 ¶¶ 71, 82, 238–241 (Dr. Graham); Ex. 2215 ¶ 22 (Dr. Thompson); *see generally* Ex. 2151 ¶¶ 5–15 (Dr. Azzalini). According to these declarants, despite the fact that the individual features of the GuideLiner device were known in the prior art, including mother-and-child catheters and catheters with a side opening, devices prior to GuideLiner did not provide an effective, reliable solution to the long standing problem of lack of backup support. Ex. 2145 ¶¶ 62–67, 82. When the various features of the prior art were combined to form the

GuideLiner device, however, the result was a new, market-making, commercially successful product that provided significant benefits over prior art devices, received praise in the art, and was copied by competitors. *Id.* ¶¶ 76, 82; Ex. 2198, 3; Ex. 2215 ¶¶ 21–23 (Dr. Thompson testifying that the GuideLiner products "fundamentally changed the way patients were treated" and allowed him "to treat patients who otherwise would have been untreatable with a catheter procedure"); Ex. 2151 ¶ 15 (Dr. Azzalini testifying that "GuideLiner made cases possible that were previously impossible, and made cases faster, safer, and more reliable").

In view of the foregoing, we find that there is a nexus between the invention recited in claims 3, 9, 14, and 19 of the '380 patent and Patent Owner's evidence of long-felt but unmet need, industry praise, and commercial success. With respect to copying, we find a nexus exists for this evidence because (1) competitors had access to the GuideLiner products and produced substantially similar designs, and (2) there is direct evidence of copying of at least a portion of the GuideLiner device by Petitioner. *See Liqwd*, 941 F.3d at 1138 ("But where there is evidence of actual copying efforts, that evidence is always relevant.").

c) Conclusion with Respect to Claims 3, 4, 9, 14, and 19

Patent Owner presents persuasive evidence that its GuideLiner products resolved a long-felt but unmet need in the art, are commercially successful, received significant praise in the industry, and were copied by competitors. Patent Owner also persuasively demonstrates a nexus between this evidence and the inventions recited in claims 3, 9, 14, and 19. Accordingly, Patent Owner's secondary considerations evidence points strongly to the nonobviousness of claims 3, 9, 14, and 19 of the '380 patent.

Considering the close case of obviousness presented by Petitioner along with the strong objective evidence of nonobviousness presented by Patent Owner, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 3, 9, 14, and 19 would have been obvious over Kontos and Adams. *See Transocean*, 699 F.3d at 1354–55. Because claim 4 depends from claim 3, and because Petitioner's arguments with respect to this claim do not overcome the issues addressed above with respect to claim 3, we also determine that Petitioner has not demonstrated by a preponderance of the evidence that claim 4 would have been obvious over Kontos and Adams.

E. Claims 8 and 18 over Kontos, Adams, and Takahashi

Claims 8 and 18 depend from claims 1 and 12, respectively, and further require that the cross-sectional inner diameter of the coaxial lumen is not more than one French smaller than the cross-sectional inner diameter of the guide catheter. Ex. 1401, 11:54–57, 13:14–17. Petitioner contends these claims would have been obvious over the combined disclosures of Kontos, Adams, and Takahashi. Pet. 72–75.

1. Takahashi

Takahashi discloses a "five-in-six" system wherein a 5 French guiding catheter is inserted into a 6 French guiding catheter to provide increased backup support. Ex. 1410, 452.[13] In this system, the 5 French catheter is 120 cm in length and the 6 French catheter is 100 cm in length. *Id.* According to Takahashi, the soft end portion of the 5 French catheter "can

[13] Our citations are to the original page numbers of the document.

easily negotiate the tortuous coronary artery with minimal damage and then it can be inserted more deeply into the artery." *Id.*

2. Analysis

Petitioner contends one of ordinary skill in the art would have sought to implement Takahashi's five-in-six system in the device of Kontos and Adams because of the increased backup support provided by the "not-more-than-one-French differential" taught by Takahashi. Pet. 73–74. Petitioner concedes that this modification would increase the diameter of Kontos's body, but contends this modification was well within the skill in the art, "as appropriately sized catheters were ubiquitous in the art." *Id.* at 74 (citing Ex. 1442 ¶¶ 109–110; Ex. 1409, 4:64–65 (Kontos noting that "[o]f course, other sizes may be used for other applications"); Ex. 1410, 452). Petitioner further contends that, for the reasons discussed for claim 3, one of ordinary skill in the art would have had a reasonable expectation of success when removing Kontos's funnel in favor of a proximal side opening. *Id.* at 73–74.

Patent Owner argues that merely removing the funnel of Kontos and "making it bigger" is not enough to meet the "one French" limitation of claims 8 and 18 because Kontos's device would still have protruding marker band structure 30 and protruding base portion 18, which would result in a greater than 1 French differential between the inner diameter of the lumen and the inner diameter of the guide catheter. PO Resp. 46.

Petitioner argues in reply that one of ordinary skill in the art could simply recess Kontos's distal marker bands and taper its pushrod for

attachment onto the "Kontos-Ressemann combination,"[14] which Petitioner contends would allow the diameter of tube 16 to be increased and permit Kontos to achieve the not-more-than-one-French differential of claims 8 and 18. Pet. Reply 21.

Petitioner's arguments with respect to claims 8 and 18 are premised on one of ordinary skill in the art removing Kontos's funnel in favor of a side opening. Pet. 73–74. As discussed above with respect to claim 3, we are not persuaded that this modification to Kontos would have been obvious. Moreover, as noted by Patent Owner, the argument that one of ordinary skill in the art would recess the marker bands and modify the pushrod structure of Kontos requires significant modifications of Kontos's device, modifications that were not proposed in the Petition. Sur-Reply 23; Pet. 72–74. The extensive need to modify Kontos's device in a way not suggested in the Petition supports Patent Owner's argument that the proposed modifications are based on a hindsight desire to recreate the claimed invention, as opposed to a known need in the art for such a device. *Id.* Accordingly, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 8 and 18 would have been obvious over Kontos, Adams, and Takahashi.

F. Claim 21 over Kontos, Adams, and Berg

Claim 21 depends from claim 20 (which depends from claim 12) and further requires that "the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or

[14] We understand the reference to the Kontos-Ressemann combination to be a typographical error that was intended to refer to the Kontos-Adams combination.

minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI." Ex. 1401, 13:29–33. Petitioner contends the subject matter of claim 21 would have been obvious over the combined disclosures of Kontos, Adams, and Berg. Pet. 75–77.

1. Berg

Berg discloses a "guiding catheter for use in coronary angioplasty and other cardiovascular interventions." Ex. 1451, Abstr. In particular, Berg discloses a guide catheter "having a transition zone with a different flexibility than adjacent portions of the catheter shaft for improved catheter performance." *Id.* at 1:21–25.

Berg notes that in order for a physician to place a catheter at the correct location in a blood vessel, the physician must apply longitudinal and rotational forces. *Id.* at 1:49–51. Thus, the catheter must be rigid enough to push through the blood vessel and torsionally rigid enough to transmit the applied torque, but flexible enough to navigate the bends in the blood vessel. *Id.* at 1:49–56. Berg also notes that "it is preferable to have a soft tip or flexible section engage the ostium," which provides a less traumatic section to the blood vessel. *Id.* at 1:63–2:4. A problem that occurs, however, is that more flexible tips may increase the incidence of guide catheter back-out, when the guide disengages from its preferred positioning in the coronary ostium. *Id.* at 2:11–15.

Berg overcomes the deficiencies of the prior art "by providing a transition element in the material," which "allows for flexibility of a guiding catheter to be increased, while maintaining its ability to prevent catheter back-out." *Id.* at 2:35–39. Figure 19 of Berg is reproduced below:

Fig.19

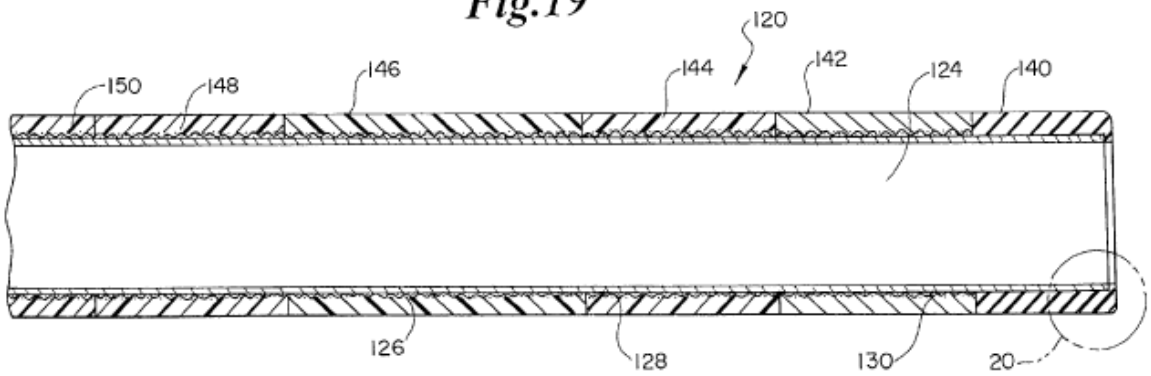


Figure 19 is a partial cross-sectional view of a distal portion of a catheter tube or guide catheter. *Id.* at 5:49–51. The guide catheter of Figure 19 has a plurality of discrete outer tubular member segments 140, 142, 144, 146, 148, and 150. *Id.* at 13:53–55. Soft tip zone 140 has a flexural modulus of "about 1 to about 15 Kpsi"; distal section zone outer tubular segment 142 has a flexural modulus of "between about 2 and about 49 Kpsi"; transition zone outer tubular segment 144 has a flexural modulus of "between about 13 and about 49 Kpsi"; secondary curve zone outer tubular segment 146 has a flexural modulus of "greater than 49 Kpsi"; mid-shaft zone outer tubular segment 148 has a flexural modulus of "about 29 to about 67 Kpsi"; and proximal shaft zone outer tubular segment 150 has a flexural modulus of "greater than 49 Kpsi to provide maximum stiffness for push and control." *Id.* at 13:66–15:6.

2. Analysis

Petitioner contends Berg discloses using a guide catheter having varying degrees of stiffness and that the flexural modulus for the first, second, and third portions of Berg's catheter overlap the ranges recited in claim 21. Pet. 75–77. Petitioner further contends that one of ordinary skill in the art would have used the flexural moduli disclosed in Berg for the

catheter of Kontos because Berg instructs that the disclosed combination of flexibilities allows the "flexibility of a guiding catheter to be increased, while maintaining its ability to prevent guide catheter back-out." *Id.* at 76 (quoting Ex. 1444, 1:36–38, 2:37–39; Ex. 1442 ¶ 117).

Patent Owner argues that one of ordinary skill in the art would not have looked to the disclosures of Berg because it is directed to a guide catheter, as opposed to an extension catheter, and emphasizes that its discrete segments should be "matched to its clinical role and function." PO Resp. 49–50 (citing Ex. 1451, 2:56–60). According to Patent Owner, these disclosures caution against importing a "one-size-fits-all" approach into different devices with different purposes and functions. *Id.* at 50 (citing Ex. 2138 ¶ 207).

Petitioner argues in reply that a person of ordinary skill in the art would look to the disclosure of Berg because Kontos's assembly and the guide catheter of Berg must navigate the same vasculature, which is the same general "clinical role and function" of the prior art combination. Pet. Reply 22.

Patent Owner does not address the combination of Kontos, Adams, and Berg in its Sur-Reply.

Although the devices are not identical, we find Petitioner's explanation persuasive as to why one of ordinary skill in the art would apply Berg's teachings of the specific flexular modulus for each portion of the device of Kontos and Adams, i.e., because the devices must navigate the same vasculature. We are also persuaded that the flexural moduli of Berg overlap the claimed flexural moduli. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) ("[E]ven a slight overlap in range establishes a *prima*

facie case of obviousness."). Accordingly, Petitioner has demonstrated by a preponderance of the evidence that claim 21 would have been obvious over Kontos, Adams, and Berg.

III. CONTINGENT MOTION TO AMEND

Having determined that claims 1 and 12 of the '380 patent are unpatentable, we address the request to add proposed substitute claims 43 and 44 as set forth in Patent Owner's Motion to Amend.

A. Legal Standard

In an *inter partes* review, amended claims are not added to a patent as a matter of right; rather, they must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). In reviewing a motion to amend, the Board assesses the patentability of the proposed substitute claims "without placing the burden of persuasion on the patent owner." *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc); *see Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019) (precedential).

Notwithstanding the foregoing, a patent owner's proposed substitute claims must meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121. *Lectrosonics*, Paper 15 at 4–8. In particular, a patent owner must demonstrate: (1) the amendment proposes a reasonable number of substitute claims; (2) the proposed claims are supported in the original disclosure (and any earlier filed disclosure for which the benefit of a filing date is sought); (3) the amendment responds to a ground of unpatentability involved in the trial; and (4) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121.

B. Proposed Substitute Claims

In its Contingent Motion to Amend, Patent Owner seeks to add proposed substitute claims 43 and 44 in place of original claims 1 and 12, respectively. Motion 1. Proposed substitute claims 43 and 44 are reproduced below, with underlining indicating text added and brackets indicating text deleted from a claim.

> 43. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:
>
> a standard 6 French guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter of at least 0.070 inches and sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and
>
> a device adapted for use with the guide catheter, including:
>
> a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a uniform, fixed cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter of at least 0.056 inches through which interventional cardiology devices, including stent catheters, are insertable while the tubular structure is located within the guide catheter; and
>
> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal

portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;

wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion; and

wherein the device is configured such that, when the flexible tip portion extends into the branch artery, the flexible tip portion and substantially rigid portion assist in resisting forces exerted by the interventional cardiology devices passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the artery.

Motion A1–3.

44. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a standard 6 French guide catheter having a continuous lumen with an internal diameter greater than or equal to 0.070 inches extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that the interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including:

an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including, in a distal-to-proximal direction:

a cylindrical flexible tip portion and a reinforced portion proximal to the flexible tip portion together defining a tubular structure with a single lumen and having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen with the guide catheter and with the tubular structure having a cross-sectional inner diameter of at least 0.056 inches through which the interventional cardiology devices are insertable; and

[a reinforced portion proximal to the flexible tip portion; and]

a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with the interventional cardiology devices that are insertable into the guide catheter; [[and]]

wherein the device further includes a substantially rigid partially cylindrical portion proximal to a distal end of the substantially rigid portion, the partially cylindrical portion defining an opening extending for a distance along a side thereof

> defined transverse to the longitudinal axis of the device that is adapted to receive the interventional cardiology devices passed through the continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, wherein the opening in the partially cylindrical portion includes a first inclined sidewall that is separated from a second inclined sidewall in the partially cylindrical portion by a non-inclined concave track; and
>
> wherein the flexible tip portion is more flexible than the reinforced portion.

Motion A3–5.

C. Statutory and Procedural Requirements

1. Reasonable Number of Substitute Claims

A patent owner may only request substitution of a reasonable number of claims. 35 U.S.C. § 316(d)(1)(B); 37 C.F.R. § 42.121(a)(3). Patent Owner presents two substitute claims, each corresponding to one original claim. Motion 1, A1–5. We find this one-for-one substitution is reasonable, and Petitioner does not assert otherwise. 37 C.F.R. § 42.121(a)(3) ("The presumption is that only one substitute claim would be needed to replace each challenged claim . . . .").

2. Whether Proposed Substitute Claims 43 and 44 Enlarge Claim Scope or Add New Matter

A proposed amendment may not seek to enlarge the scope of the claims or introduce new subject matter. 35 U.S.C. § 316(d)(3); *see* 37 C.F.R. § 42.121(a)(2)(ii); *TurboCare Div. of Demag Delaval Turbomach. Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) ("When the applicant adds a claim . . . , the new claims . . . must find support in the original specification."). Proposed substitute claims 43 and 44 seek to add or reorder limitations, and do not remove any limitations. *See, e.g.*, Motion

A1–5. Accordingly, we are persuaded that proposed substitute claims 43 and 44 do not enlarge the scope of the claims they replace.

In its Motion to Amend, Patent Owner identifies citations in the original disclosure of Application Serial No. 11/416,629 (Ex. 1403, "the '629 application") that it asserts provide support for the proposed amendment of each claim. Motion 3–8 (citations omitted). Petitioner does not argue that the substitute claims introduce new matter. *See generally* Pet. MTA Opp. Upon review of the citations identified by Patent Owner, we are persuaded that proposed substitute claims 43 and 44 are supported by the original disclosure of the '629 application.

3. Responsive to a Ground of Unpatentability

A motion to amend may be denied where it "does not respond to a ground of unpatentability involved in the trial." 37 C.F.R. § 42.121(a)(2)(i)

Patent Owner contends that the additional limitations included in proposed substitute claims 43 and 44 seek to further distinguish the prior art advanced in the Petition. Motion 9–20. Petitioner does not argue otherwise. *See generally* Pet. MTA Opp.

Upon review of Patent Owner's proposed amendments, we agree that claims 43 and 44 respond to a ground of unpatentability involved in the trial.

4. Conclusion

On this record, we determine that Patent Owner's Contingent Motion to Amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121 with respect to proposed substitute claims 43 and 44.

D. Patentability Analysis of the Proposed Substitute Claims

Petitioner challenges the patentability of proposed substitute claims 43 and 44 on the grounds that claim 44 is invalid as indefinite and claims 43 and 44 would have been obvious over the prior art of record. Pet. MTA Opp. 1. We address these challenges below.

1. Indefiniteness of Proposed Substitute Claim 44

To satisfy the definiteness requirement of § 112, a patent's claims must, when "viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014).

Petitioner contends proposed substitute claim 44 is indefinite because it "recites 'a substantially rigid portion . . . connected to . . . the flexible tip portion,' even though the claim recites an intervening 'reinforced portion.'" Pet. MTA Opp. 1 (citing Motion A3–5).

Patent Owner responds that the term "connected to" includes both direct and indirect connections, and points to the testimony of Petitioner's expert who "confirms 'the specification teaches an indirect connection, such that the flexible tip portion is connected to the reinforced portion, which is connected to the substantially rigid portion.'" PO MTA Reply 1.

As noted by Patent Owner, we are directed to no disclosure or limitation in the '380 patent that would require a direct connection, as opposed to an indirect or operable one, between the substantially rigid portion and the flexible tip portion. Indeed, the '380 patent includes embodiments that appear to require that the flexible tip portion be indirectly connected to the substantially rigid portion and not directly connected.

PO MTA Reply 2 (citing Ex. 2243 ¶ 46; Ex. 1003, 14:7–9, 16:12–19); Ex. 1401, 11:1–18. Accordingly, we do not find persuasive Petitioner's argument that proposed substitute claim 44 is indefinite due to its recitation of a connection between two elements that are not physically in contact.

2. Challenges to the Proposed Claims under 35 U.S.C. § 103(a)

Petitioner asserts in its Opposition that the proposed substitute claims are unpatentable on the following grounds:

Ground	**Claims**	**35 U.S.C. §**[15]	**References/Basis**
1	43, 44	103(a)	Itou,[16] Ressemann,[17] Kataishi[18]
2	43, 44	103(a)	Kontos, Ressemann, Takahashi
3	43, 44	103(a)	Kontos, Takahashi, Kataishi

a) Obviousness of Proposed Substitute Claims 43 and 44 over Kontos in view of Ressemann and Takahashi

Petitioner contends that proposed substitute claims 43 and 44 would have been obvious over the combined disclosures of Kontos, Ressemann, and Takahashi. Pet. MTA Opp. 15–25.

[15] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '380 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.

[16] Itou et al., US 7,736,355, issued June 15, 2010 (Ex. 1407) ("Itou").

[17] Ressemann et al., US 7,604,612, issued October 20, 2009 (Ex. 1408) ("Ressemann").

[18] Kataishi et al., US 2005/0015073, published January 20, 2005 (Ex. 1425) ("Kataishi").

(1) *Ressemann*

Ressemann is directed to an apparatus "used to prevent the introduction of emboli into the bloodstream during and after surgery performed to reduce or remove blockage in blood vessels." Ex. 1408, 1:13–16. Figure 1A of Ressemann, reproduced below, illustrates a first embodiment of a system for evacuating emboli from a blood vessel:

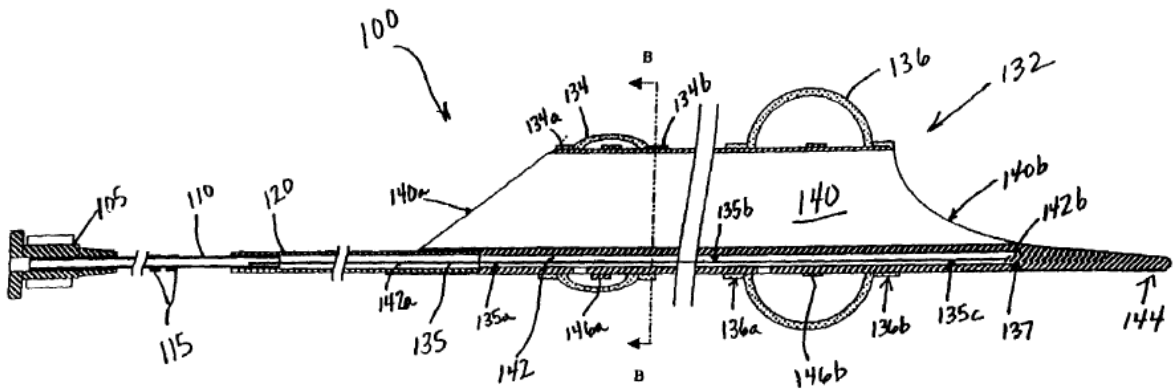


FIG. 1A

Figure 1A is a cross-sectional view of a partial length evacuation sheath and depicts evacuation sheath assembly 100, which "is sized to fit inside a guide catheter" and be advanced "into a blood vessel to treat a stenosis." *Id.* at 3:16–18, 6:18–24, Fig. 5A.

Evacuation sheath assembly 100 includes a shaft having proximal shaft portion 110, intermediate shaft portion 120, and distal shaft portion 130 (not shown in Figure 1A). *Id.* at 10:30–35. Evacuation head 132 includes multi-lumen tube 138 having evacuation lumen 140 and inflation lumen 142 and is preferably made of a relatively flexible polymer. *Id.* at 6:35–64. Evacuation lumen 140 is preferably larger than inflation lumen 142 and "is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters." *Id.* at 6:44–47.

Proximal and distal ends of evacuation lumen 140 are angled to allow for smoother passage of evacuation sheath assembly 100 through a guide catheter and to facilitate smoother passage of other therapeutic devices through evacuation lumen 140. *Id.* at 6:52–57. According to Ressemann, "[t]he larger area of the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly." *Id.* at 6:58–60.

Figure 1 B of Ressemann is reproduced below:

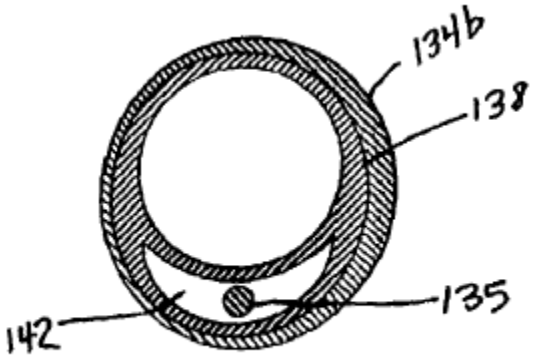


FIG. 1B

Figure 1B is a cross-sectional view of the partial length evacuation sheath of Figure 1A, taken along line 1B-1B of Figure 1A. *Id.* at 3:19–20. Figure 1B shows inflation lumen 142, which has open proximal end 142a and closed distal end 142b (shown in Figure 1A) and is designed to provide fluid to inflate balloons on evacuation head 132. *Id.* at 6:61–64. Stiffness transition member 135 is attached to the distal end of proximal shaft portion 110, "is located co-axially in the inflation lumen 142," and extends to soft tip 144. *Id.* at 11:30–39.

In use, a guiding catheter is directed to a blood vessel and then a coronary guide wire is advanced to a location just proximal to the distal tip

of the guiding catheter. *Id.* at 12:9–14. Evacuation sheath assembly 100 is then advanced over the guide wire and positioned within the blood vessel. *Id.* at 12:19–21. In this process, evacuation head 132 is positioned with its distal end within the blood vessel while its proximal end remains in the guiding catheter. *Id.* at 12:37–39. Sealing balloons 136 and 134 are then inflated to provide a fluid seal between the sealing balloons and the blood vessel. *Id.* at 12:40–45.

Figure 6D of Ressemann is reproduced below:

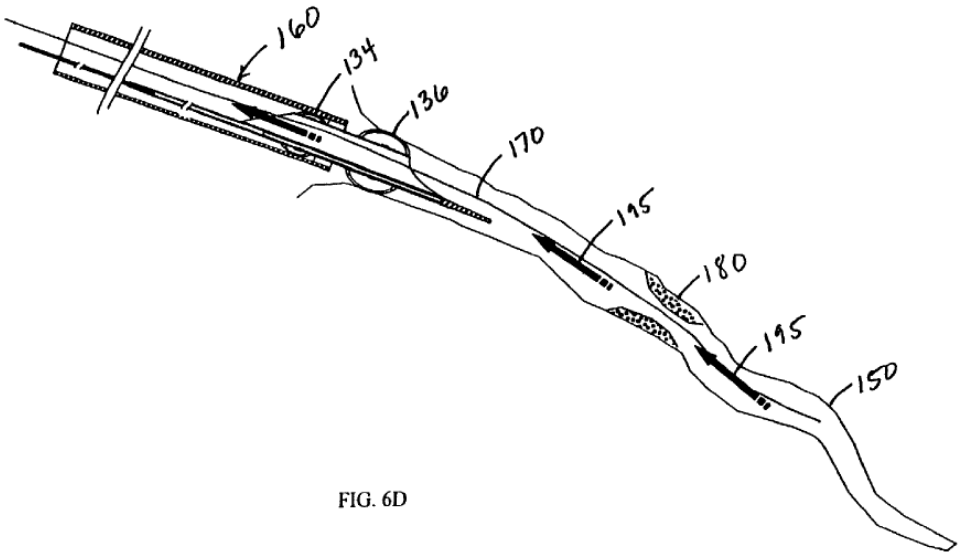


FIG. 6D

Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. *Id.* at 3:59–61. As shown in Figure 6D, guidewire 170 may be advanced beyond stenosis 180 in blood vessel 150. *Id.* at 13:3–16. A therapeutic device, such as a stent, may then be advanced over guide wire 170 and across stenosis 180. *Id.* at 13:57–60. As indicated by arrows 195, blood flow within the blood vessel is directed towards evacuation sheath 100, which "will carry any dislodged material out of the patient and into a collection chamber." *Id.* at 13:35–44.

Ressemann also discloses another embodiment where the "multi-lumen tube forming the evacuation head may include three lumens," which is illustrated in Figures 16A–16J. *Id.* at 22:29–33. Figure 16A, reproduced below, is a side view of a full-length evacuation sheath assembly 2100. *Id.* at 5:21–23.

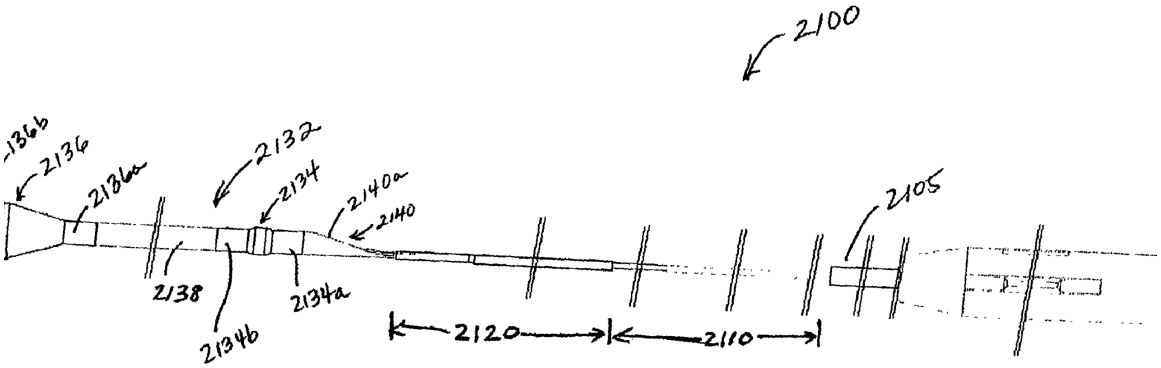


Figure 16A depicts evacuation sheath assembly 2100 having evacuation head 2132, which includes multi-lumen tube 2138 and two expandable sealing surfaces. *Id.* at 22:32–33, 22:40–41. Evacuation sheath assembly 2100 includes a shaft having two sections, a proximal shaft portion 2110 and an intermediate shaft portion 2120, each having distinct diameters. *Id.* at 27:22–36. "The proximal shaft portion 2110 provides fluid communication between an inflation apparatus (see FIG. 16I) and the intermediate shaft portion 2120." *Id*. at 27:37–38. "The intermediate shaft portion 2120 includes a tapered metallic core wire 2135 inside a polymer tube 2122." *Id.* at 27:51–53.

Evacuation head 2132 may include a structure to reinforce the proximal opening of multi-lumen tube 2138. *Id.* at 24:47–49. Figure 16J, reproduced below, is an isometric view of support collar 2141 used in evacuation sheath assembly 2100. *Id.* at 5:46–47.

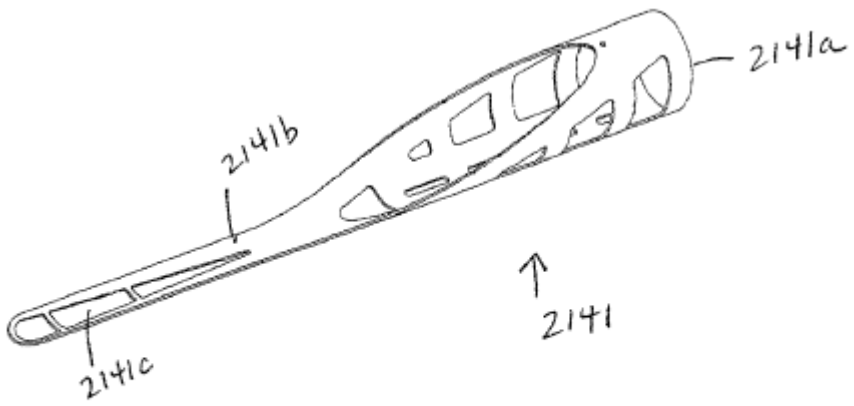


Fig. 16J

Figure 16J illustrates the structure used to reinforce the proximal opening of multi-lumen tube 2138. *Id.* at 24:47–49. Support collar 2141 includes cylindrical portion 2141*a* that fits into the proximal opening of evacuation lumen 2140 allowing support collar 2141 to reinforce the proximal opening of evacuation lumen 2140 "in the presence of deforming forces, particularly torsional stresses that may be created unintentionally by rotation of the catheter shaft near its proximal end." *Id.* at 24:49–58.

Support collar cylindrical portion 2141*a* tapers into tab portion 2141*b* that extends proximally and in a direction parallel to a longitudinal axis of evacuation lumen 2140 to provide a flexibility transition between the proximal end of evacuation head 2131 and the shaft of evacuation sheath assembly 2100. *Id.* at 24:58–67. Preferably, support collar 2141 is fabricated from a thin walled metallic tube with a series of windows 2141*c* that "allow for some flexibility and also allow for better adhesion of the encapsulation material 2133, which covers the support collar 2141, while the cylindrical portion 2141*a* maintains hoop support to the proximal opening of the evacuation lumen 2140." *Id.* at 25:1–8 (emphasis added).

Figure 16D, reproduced below, is an enlarged cross-sectional side view of the proximal end of evacuation sheath assembly 2100 and shows the placement of support collar 2141within the structure as a whole. *Id.* at 5:29–31.

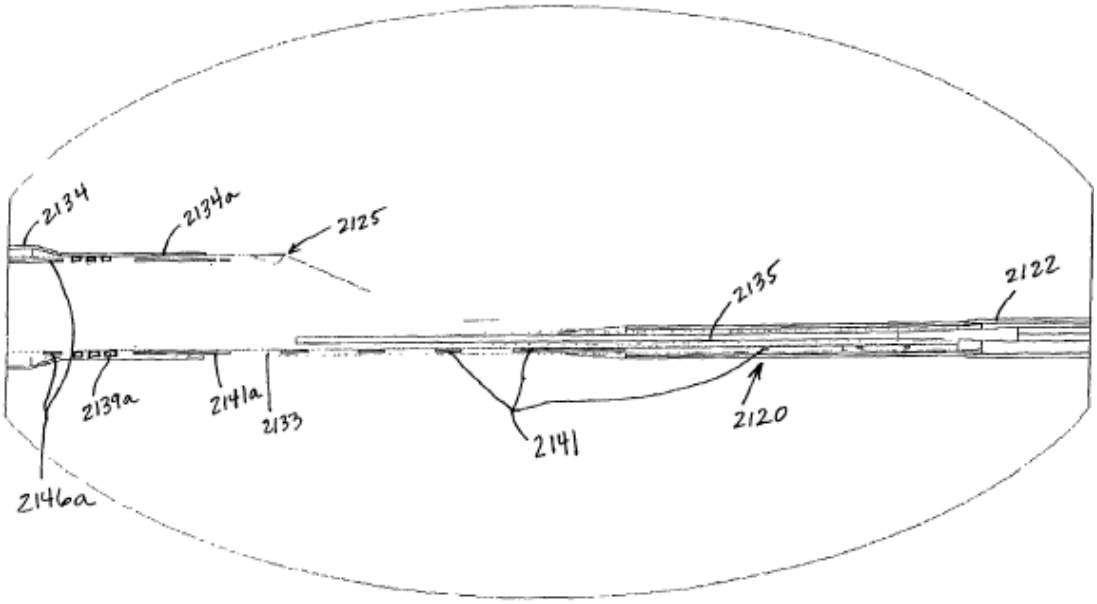


Fig. 16D

To facilitate attachment between evacuation head 2132 and intermediate shaft portion 2120, a distal portion of polymer tube 2122 is flared and flattened by heating with an appropriately formed mandrel. *Id.* at 27:59–63. As shown in Figure 16D, the "flared section is overlapped over the walls of the multi-lumen tube 2138**,** which define the core wire lumen 2143 and the inflation lumen 2142, as well as over the tab portion 2141*b* of the support collar 2141." *Id.* at 27:63–67.

(2) *Analysis*

Petitioner contends that one of ordinary skill in the art would have modified Kontos's device to include various features disclosed in Ressemann and Takahashi to arrive at the subject matter recited in proposed substitute claims 43 and 44. In particular, Petitioner contends one of ordinary skill in the art would have added reinforcing metallic braiding to tube 16 of Kontos, as is disclosed in Ressemann, in order to promote pushability and prevent kinking during advancement of the catheter. Pet. MTA Opp. 16–17. Petitioner further contends that a person of ordinary skill in the art "would have been motivated to modify Kontos to add Ressemann's support collar 2141" in order to optimize the inner diameter of tube 16, facilitate smooth reception of an interventional cardiology device as it enters the lumen, promote smoother passage of the catheter assembly, and permit smooth re-entry if the proximal end of the extension catheter was extended beyond the distal end of the guide catheter. *Id.* at 19–21. With respect to the relative sizes of the guiding catheter and support catheter of Kontos, Petitioner contends that a person of ordinary skill in the art would have sought to resize Kontos's device in order to implement Takahashi's 5-in-6 system, because Takahashi "teaches that using a catheter-in-catheter assembly—in particular, an assembly that achieves 1 French differential between the inner and outer catheters—can improve back-up support." *Id.* at 22 (citing Ex. 1902 ¶ 151; Ex. 1905 ¶¶ 138–41).

Petitioner contends that there would have been a reasonable expectation of success in making the proposed combination of Kontos, Ressemann, and Takahashi because a person of ordinary skill in the art "knew how to (i) replace the proximal funnel with a side opening, as

discussed above, and (ii) recess Kontos's distal marker bands." *Id.* (citing Ex. 1902 ¶ 154).

Petitioner's proposed combination expressly requires modifying Kontos by: (1) removing Kontos's funnel and replacing it with the side opening of Ressemann (Pet. MTA Opp. 18–21); (2) adding metallic braiding or coiling to reinforce tube 16 of Kontos (*id.* at 15–16); (3) increasing the inner diameter of Kontos's tube 16 from 0.045 inches to 0.059 inches (5 French) (*id.* at 21–22); (4) recessing Kontos's distal marker bands (*id.* at 22); and (5) tapering Kontos's pushrod (*id.* at 22–23). Dr. Brecker testifies that these expressly identified modifications would also require: (1) reconfiguring Kontos's distal soft tip 28 so that it no longer overlaps Kontos's tube 16 (Ex. 2240, 130:19–131:2); (2) potentially resizing Kontos's distal marker bands (*id.* at 131:3–134–9); (3) removing Kontos's base portion 18 (*id.* at 134:24–25, 94:14–18); (4) securing Ressemann's support collar tab 2141b on top of Kontos's pushwire, as opposed to embedding it within the structure of the catheter (*id.* at 147:9–149:21); and (5) covering the "windows" in Ressemann's collar 2141 (*id.* at 39:1–18, 137:5–13).

The sheer number of required modifications strongly suggests that Petitioner's proposed combination is based on hindsight, using the '380 patent as a roadmap. Moreover, Petitioner's proposed modifications require using Ressemann's collar in a manner that is not disclosed in Ressemann or any other recited prior art reference, i.e., resting the tab portion of Ressemann's collar on top of the catheter structure as opposed to embedding it within. *Compare* Ex. 1902 ¶ 193, *with* Ex. 1408, at 27:63–67, Fig. 16D; Ex. 2243 ¶ 97. Petitioner provides no persuasive explanation as to why one

of ordinary skill in the art would have ignored Ressemann's express teachings of embedding the tab portion of support collar 2141 within the structure of the catheter and instead redesigned (filled in Ressemann's "windows") and reoriented the tab portion to rest on the top of Kontos's pushwire in the open space within the guide catheter. Ex. 2243 ¶¶ 97, 107 (Mr. Keith noting the lack of explanation for the unique application of the tab portion of Ressemann's support collar in the proposed combined device). Accordingly, we do not find Petitioner's arguments with respect to proposed substitute claims 43 and 44 persuasive.

In addition, absent Petitioner's unsupported modification to the use of Ressemann's support collar, Petitioner's proposed device would not result in at least two different inclined regions, as recited in proposed substitute claim 44, because one of the inclined regions of Ressemann would be covered by other portions of the catheter's structure.

In view of the foregoing, we agree with Patent Owner that Petitioner fails to adequately explain why one of ordinary skill in the art would have made the proposed combination of Kontos, Ressemann, and Takahashi. Accordingly, Petitioner has not demonstrated by a preponderance of the evidence that proposed substitute claims 43 and 44 would have been obvious over Kontos, Ressemann, and Takahashi.

b) Obviousness of Proposed Substitute Claims 44 and 45 over Kontos in view of Kataishi

Petitioner contends that Kataishi also discloses a "complex side opening limitation" and, "[f]or reasons similar to those discussed above . . . a POSITA would have found it obvious to replace Kontos's flared opening

with a double-inclined opening like in Kataishi." Pet. MTA Opp. 25–26 (citing Ex. 1902 ¶¶ 207–13).

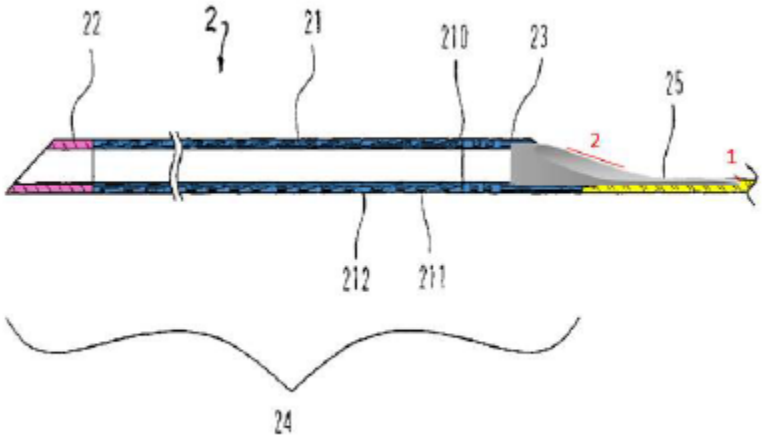
Kataishi's complex side opening is located at its *distal* tip and is used to improve suction in Kataishi's device. Ex. 1425 ¶ 1, Fig. 10. In its single paragraph addressing this proposed ground, Petitioner provides no reasoned explanation as to why one of ordinary skill in the art would have sought to implement such a suction-improving *distal* tip at the *proximal* opening of Kontos, and Petitioner's arguments related to Kontos and Ressemann do not address this issue. Nor does Petitioner persuasively explain why its motivations related to Itou (referenced in its Kontos-Kataishi ground) would necessarily translate to the distal opening of Kontos.

In any event, Mr. Keith persuasively testifies that the distal tip of Kataishi would increase flexibility at the proximal opening of Kontos, creating a kink point. Ex. 2243 ¶ 131 ("While increased flexibility at the distal end provides increased suction, flexibility at the proximal opening of the catheter would increase the risk of kinking."); *see also id.* ¶¶ 119–132 (generally refuting Petitioner's reasons for combining Kontos and Kataishi). We credit this testimony and, given the negative effects resulting from the importation of Kataishi's distal opening at Kontos's proximal opening, we find that Petitioner's unpatentability arguments based on Kontos and Kataishi are unpersuasive.

c) Obviousness of Proposed Substitute Claims 43, 44 over Itou in view of Ressemann or Kataishi

Petitioner contends that proposed substitute claims 43 and 44 would have been obvious over Itou[19] in view of Ressemann and Kataishi. Pet. MTA Opp. 2–15.

In this ground, Petitioner contends that one of ordinary skill in the art would have implemented Ressemann's support collar at the proximal opening of Itou's catheter. *Id.* at 9–10. Petitioner provides an annotated figure showing its proposed combination of Itou and Ressemann



The figure reproduced above shows Petitioner's proposed combination of Itou and Ressemann. *Id.*

[19] In our Final Written Decision in IPR2020-00128, we conclude that Itou is not prior art to the claims of the '380 patent challenged in that proceeding (as well as this proceeding) in view of an earlier conception and reduction to practice. *See* IPR2020-00128, Paper 127. Patent Owner does not provide claim charts or other evidence, however, demonstrating that the inventions recited in proposed substitute claims 43 and 44, when considered as a whole, were conceived and reduced to practice prior to the effective filing date of Itou. As such, we address the merits of Petitioner's proposed combination of Itou, Ressemann, and Kataishi.

As shown in Petitioner's annotated figure, Petitioner proposes to use Ressemann's support collar 2141 in Itou in a tab-on-top configuration, with the tab portion resting on Itou's metal pushwire. *Id.* at 10; PO MTA Reply 8–9. But Petitioner again fails to explain why one of ordinary skill in the art would have ignored Ressemann's express teachings of embedding the tab portion of support collar 2141 deep within the structure of the catheter, and instead laid the tab portion on top of Itou's metal pushwire. *See* PO MTA Reply 8–9; *see also id.* at 7 (noting that Petitioner's proposed combination would require at least six different modifications to the combined device). Thus, we do not find Petitioner's reasons for combining Itou and Ressemann persuasive.

Accordingly, Petitioner's arguments with respect to the combination of Itou, Ressemann, and Kataishi are not persuasive.

3. Conclusions with Respect to Obviousness of Proposed Substitute Claims 43 and 44

For the reasons discussed above, we determine that Petitioner has not demonstrated by a preponderance of the evidence that proposed substitute claims 43 and 44 would have been obvious over Itou in view of Ressemann or Kataishi, over Kontos in view of Ressemann and Takahashi, or over Kontos in view of Kataishi. Accordingly, we grant Patent Owner's Contingent Motion to Amend.

IV. CONSTITUTIONAL CHALLENGE

Patent Owner argues that the Petition should be denied because "the manner in which administrative law judges are appointed is unconstitutional." PO Resp. 76 (citing *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1325 (Fed. Cir. 2019)). Patent Owner further argues

that the remedy in the *Arthrex* decision "severing certain removal protections, is insufficient to cure the constitutional defect, because, e.g., it still does not give a properly appointed principle office the power to review administrative law judge decisions." *Id.* (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018)). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

V. CONCLUSION[20]

For the foregoing reasons, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1, 2, 6, 7, 12, 13, 15–17, 20, and 21 are unpatentable as having been obvious over Petitioner's Kontos-based grounds. Petitioner has not shown by a preponderance of the evidence, however, that claims 3, 4, 8, 9, 14, 18, and 19 are unpatentable.

With respect to Patent Owner's Contingent Motion to Amend, we determine that Petitioner has not demonstrated by a preponderance of the evidence that proposed substitute claims 43 and 44 would have been unpatentable as having been obvious over Itou in view of Ressemann or Kataishi, Kontos in view of Ressemann and Takahashi, or Kontos in view of

[20] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

Kataishi. Accordingly, Patent Owner Contingent Motion to Amend is granted.

In summary:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–4, 6, 7, 9, 12–17, 19, 20	103	Kontos, Adams	1, 2, 6, 7, 12, 13, 15–17, 20	3, 4, 9, 14, 19
8, 18	103	Kontos, Adams, Takahashi		8, 18
21	103	Kontos, Adams, Berg	21	
Overall Outcome			1, 2, 6, 7, 12, 13, 15–17, 20, 21	3, 4, 8, 9, 14, 18, 19

The table below summarizes our conclusions as to Patent Owner's Revised Motion to Amend the claims.

Motion to Amend Outcome	Claim(s)
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	43, 44
Substitute Claims: Motion to Amend Granted	43, 44
Substitute Claims: Motion to Amend Denied	
Substitute Claims: Not Reached	

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner demonstrates by a preponderance of the evidence that claims 1, 2, 6, 7, 12, 13, 15–17, 20, and 21 of U.S. Patent No. RE45,380 are unpatentable;

FURTHER ORDERED that Petitioner has not demonstrated by a preponderance of the evidence that claims 3, 4, 8, 9, 14, 18, and 19 are unpatentable;

FURTHER ORDERED that Patent Owner's Contingent Motion to Amend U.S. Patent No. RE45,380 to add proposed substitute claim 43 and 44 is granted; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

FOR PETITIONER:
Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com

FOR PATENT OWNER:
Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com

EXHIBIT B

Trials@uspto.gov
571.272.7822

Paper 107
Entered: August 27, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDERSECRETARY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

MEDTRONIC, INC. and MEDTRONIC VASCULAR, INC.,
Petitioner,

v.

TELEFLEX INNOVATIONS S.À.R.L.,
Patent Owner.

IPR2020-00127 (Patent 8,043,032 B2)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00136 (Patent RE45,776 E)

Before ANDREW HIRSHFELD, *Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

ORDER

The Office has received a request for Director review of the Final Written Decision in each of these cases. *See, e.g.*, IPR2020-00127, Ex. 3100. Each request was referred to Mr. Hirshfeld, Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

It is ORDERED that the request for Director review in each case is denied; and

FURTHER ORDERED that the Patent Trial and Appeal Board's Final Written Decision in each case is the final decision of the agency.

FOR PETITIONER:

Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
Emily J. Tremblay
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com
etremblay@robinskaplan.com

FOR PATENT OWNER:

Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com